CRITICAL THERAPEUTICS INC
Form S-4/A
September 29, 2008

Table of Contents

**As filed with the Securities and Exchange Commission on September 29, 2008**
**Registration No. 333-152442**

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

**AMENDMENT NO. 3**
**TO**

**FORM S-4**
**REGISTRATION STATEMENT**
**UNDER**
**THE SECURITIES ACT OF 1933**

**CRITICAL THERAPEUTICS, INC.**
*(Exact name of Registrant as specified in its charter)*

| **Delaware** | **000-50767** | **04-3523569** |
|---|---|---|
| *(State or other jurisdiction of incorporation or organization)* | *(Primary Standard Industrial Classification Code Number)* | *(I.R.S. Employer Identification Number)* |

**60 Westview Street**
**Lexington, MA 02421**
**(781) 402-5700**
*(Address, including zip code, and telephone number, including area code, of Registrant s principal executive offices)*

**Trevor Phillips, Ph.D.**
**President and Chief Executive Officer**
**Critical Therapeutics, Inc.**
**60 Westview Street**
**Lexington, MA 02421**
**Telephone: (781) 402-5700**
**Facsimile: (781) 862-5691**
*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

*Copies To:*

**Steven D. Singer, Esq.**
**Michael J. LaCascia, Esq.**
**Brian A. Johnson, Esq.**
**Wilmer Cutler Pickering Hale and Dorr LLP**
**399 Park Avenue**
**New York, NY 10022**
**Telephone: (212) 230-8800**
**Facsimile: (212) 230-8888**

**Scott B. Townsend, Esq.**
**General Counsel, Senior Vice President of**
**Legal Affairs and Secretary**
**Critical Therapeutics, Inc.**
**60 Westview Street**
**Lexington, MA 02421**
**Telephone: (781) 402-5700**
**Facsimile: (781) 862-5691**

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effectiveness of this registration statement and the satisfaction or waiver of all other conditions under the merger agreement described herein.

If the securities being registered on this Form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) 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. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) 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. o

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.

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

**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 that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

Table of Contents

The information in this proxy statement/prospectus is not complete and may be changed. Critical Therapeutics may not sell its securities pursuant to the proposed transaction until the Registration Statement filed with the Securities and Exchange Commission is effective. This proxy statement/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 SEPTEMBER 29, 2008**

**SPECIAL MEETING OF STOCKHOLDERS**
**MERGER PROPOSED YOUR VOTE IS VERY IMPORTANT**

To the Stockholders of Critical Therapeutics, Inc.:

On May 1, 2008, Critical Therapeutics, Inc., which we refer to as Critical Therapeutics, and Cornerstone BioPharma Holdings, Inc., which we refer to as Cornerstone, entered into a merger agreement pursuant to which Neptune Acquisition Corp., a wholly owned subsidiary of Critical Therapeutics, which we refer to as the transitory subsidiary, will merge with and into Cornerstone, with Cornerstone continuing after the merger as the surviving company and a wholly owned subsidiary of Critical Therapeutics.

At the effective time of the merger, all outstanding shares of Cornerstone s common stock will be converted into and exchanged for shares of Critical Therapeutics common stock and all outstanding options, whether vested or unvested, and all outstanding warrants to purchase Cornerstone s common stock will be assumed by Critical Therapeutics and become options and warrants to purchase Critical Therapeutics common stock. Pursuant to the merger, Critical Therapeutics will issue to Cornerstone s stockholders, and will assume Cornerstone options and warrants that will represent, an aggregate of approximately 101.5 million shares of Critical Therapeutics common stock, subject to adjustment as a result of a reverse stock split of Critical Therapeutics common stock to occur in connection with the merger. Immediately following the effective time of the merger, Cornerstone s stockholders will own approximately 70%, and Critical Therapeutics current stockholders will own approximately 30%, of Critical Therapeutics common stock, assuming the exchange or conversion prior to the merger of the outstanding principal amount of a note issued by a wholly owned subsidiary of Cornerstone into shares of Cornerstone s common stock and after giving effect to shares issuable pursuant to Cornerstone s outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics outstanding options and warrants. The exact exchange ratio per share of Cornerstone s common stock will be based in part on the number of shares of Cornerstone s common stock outstanding or issuable pursuant to outstanding options and warrants immediately prior to the effective time of the merger and will not be calculated until that time.

Shares of Critical Therapeutics common stock are currently listed on The NASDAQ Capital Market under the symbol CRTX. After completion of the merger, Critical Therapeutics will be renamed Cornerstone Therapeutics Inc. and expects to continue to trade under the symbol CRTX on The NASDAQ Capital Market in connection with the listing of Critical Therapeutics common stock pursuant to NASDAQ Marketplace Rule 4340. Following the merger, Critical Therapeutics will appoint new directors and executive officers designated by Cornerstone, and the headquarters of Critical Therapeutics will be located in Cary, North Carolina, at Cornerstone s headquarters. On , 2008, the last trading day before the date of this proxy statement/prospectus, the closing sale price per share of Critical Therapeutics common stock as reported on The NASDAQ Capital Market was $ per share.

Critical Therapeutics is holding a special meeting of stockholders in order to obtain the stockholder approvals necessary to complete the merger. At the special meeting, which will be held at 10:00 a.m., local time, on October 31, 2008, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, located at 60 State Street, Boston, Massachusetts 02109, unless postponed or adjourned to a later date, Critical Therapeutics will ask its stockholders to approve the issuance of Critical Therapeutics common stock pursuant to the merger agreement, approve an amendment to Critical Therapeutics certificate of incorporation to effect a reverse stock split of Critical Therapeutics common stock, as described below, referred to as the reverse stock split, and approve an amendment to Critical Therapeutics certificate of incorporation to change the name of Critical Therapeutics to Cornerstone Therapeutics Inc. Upon the effectiveness of the amendment to Critical Therapeutics certificate of incorporation effecting the reverse stock split, the outstanding shares of Critical Therapeutics common stock will be reclassified and combined into a lesser number of shares to be determined by Critical Therapeutics board of directors prior to the effective time of such amendment and publicly announced by Critical Therapeutics.

After careful consideration, Critical Therapeutics board of directors has unanimously approved the merger agreement and the proposals referred to above, and has determined that they are advisable, fair to and in the best interests of Critical Therapeutics stockholders. **Accordingly, Critical Therapeutics board of directors unanimously recommends that stockholders vote FOR the issuance of Critical Therapeutics common stock pursuant to the merger agreement, FOR the amendment to Critical Therapeutics certificate of**

Table of Contents

**incorporation to effect the reverse stock split and FOR the amendment to Critical Therapeutics certificate of incorporation to change the name of Critical Therapeutics to Cornerstone Therapeutics Inc.**

More information about Critical Therapeutics, Cornerstone and the proposed transaction is contained in the accompanying proxy statement/prospectus. **Critical Therapeutics urges you to read the proxy statement/prospectus carefully and in its entirety. IN PARTICULAR, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DISCUSSED UNDER RISK FACTORS BEGINNING ON PAGE 24.**

**Your vote is important.** Whether or not you expect to attend the special meeting in person, please complete, date, sign and promptly return the accompanying proxy card in the enclosed postage paid envelope to ensure that your shares will be represented and voted at the special meeting.

Critical Therapeutics is excited about the opportunities the merger brings to its stockholders, and we thank you for your consideration and continued support.

Yours sincerely,

Trevor Phillips, Ph.D.
*President and Chief Executive Officer*

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved the merger described in this proxy statement/prospectus or the Critical Therapeutics common stock to be issued in connection with the merger or determined if this proxy statement/prospectus is accurate or adequate. Any representation to the contrary is a criminal offense.**

This proxy statement/prospectus is dated , 2008, and is first being mailed to stockholders on or about , 2008.

Table of Contents

**CRITICAL THERAPEUTICS, INC.**
**60 WESTVIEW STREET**
**LEXINGTON, MASSACHUSETTS 02421**

**NOTICE OF SPECIAL MEETING OF STOCKHOLDERS**
**To Be Held On October 31, 2008**

To the Stockholders of Critical Therapeutics, Inc.:

A special meeting of stockholders of Critical Therapeutics, Inc. will be held at 10:00 a.m., local time, on October 31, 2008, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, located at 60 State Street, Boston, Massachusetts 02109, to consider and act upon the following matters:

1. To approve the issuance of Critical Therapeutics common stock pursuant to the Agreement and Plan of Merger, dated as of May 1, 2008, by and among Critical Therapeutics, Neptune Acquisition Corp., a wholly owned subsidiary of Critical Therapeutics, and Cornerstone BioPharma Holdings, Inc.

2. To approve an amendment to Critical Therapeutics certificate of incorporation to effect a reverse stock split of Critical Therapeutics common stock.

3. To approve an amendment to Critical Therapeutics certificate of incorporation to change the name of Critical Therapeutics to Cornerstone Therapeutics Inc.

4. To consider and vote upon an adjournment of the special meeting, if necessary, if a quorum is present, to solicit additional proxies if there are not sufficient votes in favor of Proposals 1, 2 and 3.

Stockholders also will consider and act on any other matters as may properly come before the special meeting or any adjournment or postponement thereof, including any procedural matters incident to the conduct of the special meeting.

September 29, 2008 is the record date for the determination of stockholders entitled to notice of, and to vote at, the special meeting and any adjournment or postponement thereof. Only holders of record of shares of Critical Therapeutics common stock at the close of business on the record date are entitled to notice of, and to vote at, the special meeting. At the close of business on the record date, Critical Therapeutics had shares of common stock outstanding and entitled to vote at the special meeting.

**Your vote is important. The affirmative vote of the holders of a majority of the shares of Critical Therapeutics common stock present in person or represented by proxy and voting on such matter at the special meeting is required for approval of Proposal 1 and Proposal 4 above. The affirmative vote of holders of a majority of the outstanding shares of Critical Therapeutics common stock as of the record date for the special meeting is required for approval of Proposal 2 and Proposal 3 above.**

**Whether or not you plan to attend the special meeting in person, please complete, date, sign and promptly return the accompanying proxy card in the enclosed postage paid envelope to ensure that your shares will be represented and voted at the special meeting. If you date, sign and return your proxy card without indicating**

**how you wish to vote, your proxy will be counted as a vote in favor of Proposals 1 through 4. If you fail either to return your proxy card or vote in person at the special meeting, your shares will not be counted for purposes of determining whether a quorum is present at the special**

Table of Contents

**meeting and will have the same effect as a vote against Proposal 2 and Proposal 3. If you attend the special meeting, you may, upon your written request, withdraw your proxy and vote in person.**

By Order of the Board of Directors of
Critical Therapeutics, Inc.

Scott B. Townsend, Esq.
*Secretary*

, 2008
Lexington, Massachusetts

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS HAS DETERMINED AND BELIEVES THAT EACH OF THE PROPOSALS OUTLINED ABOVE IS ADVISABLE, FAIR TO AND IN THE BEST INTERESTS OF CRITICAL THERAPEUTICS AND ITS STOCKHOLDERS AND HAS UNANIMOUSLY APPROVED EACH SUCH PROPOSAL. CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR EACH SUCH PROPOSAL.**

Table of Contents

## REFERENCES TO ADDITIONAL INFORMATION

This proxy statement/prospectus forms a part of a registration statement on Form S-4 (Registration No. 333-152442) filed by Critical Therapeutics, Inc., or Critical Therapeutics, with the U.S. Securities and Exchange Commission, or SEC. It constitutes a prospectus of Critical Therapeutics under Section 5 of the Securities Act of 1933, as amended, or the Securities Act, and the rules thereunder, with respect to the shares of Critical Therapeutics common stock to be issued to holders of common stock of Cornerstone BioPharma Holdings, Inc., or Cornerstone, in the merger. In addition, it constitutes a proxy statement under Section 14(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules thereunder, and a notice of meeting with respect to the special meeting of stockholders at which Critical Therapeutics stockholders will consider and vote on the proposals to approve the issuance of Critical Therapeutics common stock issuable to the holders of Cornerstone s common stock pursuant to the merger agreement described in this proxy statement/prospectus, an amendment to Critical Therapeutics certificate of incorporation to effect a reverse stock split of Critical Therapeutics common stock and an amendment to Critical Therapeutics certificate of incorporation to change the name of Critical Therapeutics to Cornerstone Therapeutics Inc.

This proxy statement/prospectus incorporates important business and financial information about Critical Therapeutics that is not included in or delivered with this proxy statement/prospectus. This information is available to you without charge upon your written or oral request. You can obtain these documents, which are incorporated by reference in this proxy statement/prospectus, by requesting them in writing or by telephone at the following address and telephone number:

**CRITICAL THERAPEUTICS, INC.**
Thomas P. Kelly
Chief Financial Officer
60 Westview Street
Lexington, Massachusetts 02421
Tel: (781) 402-5700

**IF YOU WOULD LIKE TO REQUEST DOCUMENTS, PLEASE DO SO BY , 2008 IN ORDER TO RECEIVE THEM BEFORE THE SPECIAL MEETING.**

See Where You Can Find More Information beginning on page 352.

## NOTE REGARDING TRADEMARKS

Zyflo® and Zyflo CR® are registered trademarks of Critical Therapeutics.

Cornerstone BioPharma, Inc.®, AlleRx®, Balacet® and Deconsal® are registered trademarks, and Aristos Pharmaceuticals™, Cornerstone Therapeutics Inc.™, HyoMax™ and RespiVent™ are trademarks, of Cornerstone. Spectracef® is a registered trademark of Meiji Seika Kaisha, Ltd.

The other trademarks, trade names and service marks appearing in this proxy statement/prospectus are the property of their respective holders.

Table of Contents

## TABLE OF CONTENTS

**Table of Contents**

**Table of Contents**

**Table of Contents**

Table of Contents

## QUESTIONS AND ANSWERS ABOUT THE SPECIAL MEETING AND THE MERGER

Except as specifically indicated, the following information and all other information contained in this proxy statement/prospectus does not give effect to the reverse stock split described in Proposal 2.

The following section provides answers to frequently asked questions about the special meeting of stockholders and the merger. This section, however, only provides summary information. These questions and answers may not address all issues that may be important to you as a stockholder. For a more complete response to these questions and for additional information, please refer to the cross-referenced pages below. You should carefully read this entire proxy statement/prospectus, including each of the annexes.

**Q: What is the merger?**

A: Critical Therapeutics and Cornerstone have entered into an Agreement and Plan of Merger, dated as of May 1, 2008, or the merger agreement, that contains the terms and conditions of the proposed business combination of Critical Therapeutics and Cornerstone. Under the merger agreement, Cornerstone and Neptune Acquisition Corp., a wholly owned subsidiary of Critical Therapeutics, or the transitory subsidiary, will merge, with Cornerstone surviving as a wholly owned subsidiary of Critical Therapeutics. This transaction is referred to as the merger.

**Q: How many shares of Critical Therapeutics common stock will be issued or become issuable pursuant to the merger?**

A: Pursuant to the merger, Critical Therapeutics will issue to Cornerstone s stockholders, and will assume Cornerstone options and warrants that will represent, an aggregate of approximately 101.5 million shares of Critical Therapeutics common stock, subject to adjustment as a result of a reverse stock split of Critical Therapeutics common stock to occur in connection with the merger.

**Q: What percentage of Critical Therapeutics common stock will this represent?**

A: Immediately following the effective time of the merger, Cornerstone s stockholders will own approximately 70%, and Critical Therapeutics current stockholders will own approximately 30%, of Critical Therapeutics common stock, assuming the exchange or conversion prior to the merger of the outstanding principal amount of a note issued by a wholly owned subsidiary of Cornerstone into shares of Cornerstone s common stock and after giving effect to shares issuable pursuant to Cornerstone s outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics outstanding options and warrants.

**Q: What is the reverse stock split and why is it necessary?**

A: Immediately prior to the effective time of the merger, the outstanding shares of Critical Therapeutics common stock will be reclassified and combined into a lesser number of shares to be determined by Critical Therapeutics board of directors prior to the effective time and publicly announced by Critical Therapeutics. Because The NASDAQ Capital Market s initial listing standards require Critical Therapeutics to have, among other things, a $4.00 per share minimum bid price, the reverse stock split is necessary to consummate the merger.

**Q: What will happen to Critical Therapeutics if, for any reason, the merger with Cornerstone does not close?**

A:

Critical Therapeutics has invested significant time and incurred, and expects to continue to incur, significant expenses related to the proposed merger with Cornerstone. In the event the merger does not close, Critical Therapeutics will have a limited ability to continue its current operations without obtaining additional financing. Although Critical Therapeutics board of directors may elect to, among other things, attempt to complete another strategic transaction if the merger with Cornerstone does not close, Critical Therapeutics board of directors may instead divest all or a portion of Critical Therapeutics business or take steps necessary to liquidate or dissolve Critical Therapeutics business and assets if a viable alternative strategic transaction is not available.

Table of Contents

**Q: Why am I receiving this proxy statement/prospectus?**

A: You are receiving this proxy statement/prospectus because you have been identified as a stockholder of Critical Therapeutics as of the record date, and thus you are entitled to vote at Critical Therapeutics special meeting. This document serves as both a proxy statement used to solicit proxies for the special meeting and as a prospectus used to offer shares of Critical Therapeutics common stock in exchange for shares of Cornerstone s common stock pursuant to the terms of the merger agreement. This document contains important information about the merger and the special meeting of Critical Therapeutics, and you should read it carefully.

**Q: Who is soliciting my proxy?**

A: This proxy is being solicited by Critical Therapeutics board of directors.

**Q: What stockholder approvals are required to consummate the merger?**

A: To consummate the merger, Critical Therapeutics stockholders must approve:

- the issuance of shares of Critical Therapeutics common stock in the merger, which requires the affirmative vote of the holders of a majority of the shares of Critical Therapeutics common stock present in person or represented by proxy and voting on such matter at the special meeting;

- the amendment to Critical Therapeutics certificate of incorporation to effect the reverse stock split of Critical Therapeutics common stock, which requires the affirmative vote of holders of a majority of the outstanding shares of Critical Therapeutics common stock as of the record date for the special meeting; and

- the amendment to Critical Therapeutics certificate of incorporation to change the name of Critical Therapeutics to Cornerstone Therapeutics Inc. , which requires the affirmative vote of the holders of a majority of the outstanding shares of Critical Therapeutics common stock as of the record date for the special meeting.

In addition, Cornerstone s stockholders must adopt the merger agreement, which requires the affirmative vote of holders of a majority of the outstanding shares of Cornerstone s common stock. On May 2, 2008, holders of a majority of Cornerstone s outstanding shares of common stock adopted the merger agreement pursuant to written consents in lieu of a meeting.

**Q: How does Critical Therapeutics board of directors recommend that Critical Therapeutics stockholders vote?**

A: After careful consideration, Critical Therapeutics board of directors has unanimously approved the merger agreement and each of the proposals described in this proxy statement/prospectus that the stockholders of Critical Therapeutics are being asked to consider, and has determined that they are advisable, fair to and in the best interests of Critical Therapeutics stockholders. Accordingly, Critical Therapeutics board of directors unanimously recommends that Critical Therapeutics stockholders vote FOR each such proposal.

**Q: How did Cornerstone s board of directors recommend that Cornerstone s stockholders vote?**

A: After careful consideration, Cornerstone s board of directors unanimously recommended that Cornerstone s stockholders vote to adopt the merger agreement.

**Q: When do you expect the merger to be consummated?**

A: Critical Therapeutics and Cornerstone anticipate that the consummation of the merger will occur in the fourth quarter of 2008 as promptly as practicable after the special meeting and following satisfaction or waiver of all closing conditions. However, the exact timing of the consummation of the merger is not yet known.

Table of Contents

**Q: What do I need to do now?**

A: You are urged to read this proxy statement/prospectus carefully, including each of the annexes, and to consider how the merger affects you. If your shares are registered directly in your name, you may vote in one of four different ways. First, you can provide your proxy instructions over the Internet at the web site of Critical Therapeutics tabulator, BNY Mellon Shareowner Services, at http://www.proxyvoting.com/crtx, by following the instructions you will find there. Second, you can provide your proxy instructions by telephone at (866) 540-5760 toll-free from the United States or Canada, by following the instructions. Third, you can complete, date and sign the enclosed proxy card and mail it in the enclosed postage-paid envelope to BNY Mellon Shareowner Services. Alternatively, you can deliver your completed proxy card in person or vote by completing a ballot in person at the special meeting.

**Q: What happens if I do not return a proxy card or otherwise provide proxy instructions?**

A: The failure to return your proxy card or otherwise provide proxy instructions will have the same effect as voting against Proposal 2 and Proposal 3, and your shares will not be counted for purposes of determining whether a quorum is present at the special meeting.

**Q: May I vote in person?**

A: If you are a stockholder of Critical Therapeutics and your shares of Critical Therapeutics common stock are registered directly in your name with Critical Therapeutics transfer agent, you are considered, with respect to those shares, the stockholder of record, and the proxy materials and proxy card are being sent directly to you by Critical Therapeutics. If you are a Critical Therapeutics stockholder of record, you may attend the special meeting to be held on October 31, 2008 and vote your shares in person, rather than signing and returning your proxy.

If your shares of Critical Therapeutics common stock are held by a bank, broker or other nominee, you are considered the beneficial owner of shares held in street name, and the proxy materials are being forwarded to you together with a voting instruction card. As the beneficial owner, you are also invited to attend the special meeting. Since a beneficial owner is not the stockholder of record, you may not vote these shares in person at the special meeting unless you obtain a proxy from your broker issued in your name giving you the right to vote the shares at the special meeting.

**Q: If my Critical Therapeutics shares are held in street name by my broker, will my broker vote my shares for me?**

A: Your broker will not be able to vote your shares of Critical Therapeutics common stock without specific instructions from you. You should instruct your broker to vote your shares, following the procedure provided by your broker.

**Q: May I change my vote after I have submitted a proxy or provided proxy instructions?**

A: Any Critical Therapeutics stockholder of record voting by proxy, other than those Critical Therapeutics stockholders who have executed a voting agreement and irrevocable proxy, has the right to revoke the proxy at any time before the polls close at the special meeting by sending a written notice stating that it would like to revoke its proxy to the Secretary of Critical Therapeutics, by voting again over the Internet or by telephone, by providing a duly executed proxy card bearing a later date than the proxy being revoked or by attending the special meeting and voting in person. Attendance alone at the special meeting will not revoke a proxy. If a

stockholder of Critical Therapeutics has instructed a broker to vote its shares of Critical Therapeutics common stock that are held in street name, the stockholder must follow directions received from its broker to change those instructions.

**Q: Should Cornerstone s and Critical Therapeutics stockholders send in their stock certificates now?**

A: No. After the merger is consummated, Cornerstone s stockholders will receive written instructions from the exchange agent for exchanging their certificates representing shares of Cornerstone capital stock for certificates representing shares of Critical Therapeutics common stock. Cornerstone s stockholders will also receive a cash payment for any fractional shares.

Table of Contents

In addition, Critical Therapeutics stockholders will receive written instructions, as applicable, from Critical Therapeutics transfer agent for exchanging their certificates representing shares of Critical Therapeutics common stock for new certificates giving effect to the reverse stock split. Critical Therapeutics stockholders will also receive a cash payment for any fractional shares.

**Q: Who is paying for this proxy solicitation?**

A: Critical Therapeutics will bear the cost of soliciting proxies, including the printing, mailing and filing of this proxy statement/prospectus, the proxy card and any additional information furnished to Critical Therapeutics stockholders. Critical Therapeutics has engaged Morrow & Co., LLC, a proxy solicitation firm, to solicit proxies from Critical Therapeutics stockholders. Arrangements will also be made with banks, brokers, nominees, custodians and fiduciaries who are record holders of Critical Therapeutics common stock for the forwarding of solicitation materials to the beneficial owners of Critical Therapeutics common stock. Critical Therapeutics will reimburse these banks, brokers, nominees, custodians and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials.

**Q: Who can provide me with additional information and help answer my questions?**

A: If you would like additional copies, without charge, of this proxy statement/prospectus or if you have questions about the merger and the other proposals being considered at the special meeting, including the procedures for voting your shares, you should contact Morrow & Co., LLC, Critical Therapeutics proxy solicitor, by telephone at 1-800-607-0088 or by email at crtx.info@morrowco.com.

Table of Contents

## SUMMARY

*This summary highlights selected information from this proxy statement/prospectus and may not contain all of the information that is important to you. To better understand the merger and the other proposals being considered at the special meeting, you should read this entire proxy statement/prospectus carefully, including the materials attached as annexes, as well as other documents referred to or incorporated by reference herein. See Where You Can Find More Information beginning on page 352 of this proxy statement/prospectus. Page references are included in parentheses to direct you to a more detailed description of the topics presented in this summary.*

### The Companies

**Critical Therapeutics, Inc.**
60 Westview Street
Lexington, Massachusetts 02421
(781) 402-5700

Critical Therapeutics is a biopharmaceutical company focused on developing and commercializing products for respiratory and inflammatory diseases. Critical Therapeutics owns worldwide rights to two marketed products: ZYFLO CR® (zileuton) extended-release tablets, or ZYFLO CR, which the U.S. Food and Drug Administration, or FDA, approved in May 2007, and ZYFLO® (zileuton tablets), or ZYFLO, which the FDA approved in 1996, for the prevention and chronic treatment of asthma in adults 12 years of age or older. Critical Therapeutics also is developing an injectable formulation of zileuton, or zileuton injection, for use in the hospital emergency department for the treatment of acute asthma attacks. In June 2008, Critical Therapeutics announced the results from its Phase II clinical trial with zileuton injection in patients with chronic, stable asthma. In addition, Critical Therapeutics is developing other product candidates directed toward the body s inflammatory response. Critical Therapeutics has conducted preclinical work in its alpha-7 nicotinic acetylcholine receptor program, or alpha-7 program, for the treatment of severe acute inflammatory disease. Critical Therapeutics also has collaboration agreements with third parties for the development of monoclonal antibodies directed toward a cytokine called high mobility group box protein 1, or HMGB1, and a diagnostic directed toward measuring HMGB1 in the bloodstream. Both of these programs are in preclinical stages of development.

**Cornerstone BioPharma Holdings, Inc.**
2000 Regency Parkway, Suite 255
Cary, North Carolina 27518
(888) 466-6505

Cornerstone is a specialty pharmaceutical company focused on acquiring, developing and commercializing prescription products for the respiratory market. Cornerstone currently promotes four marketed products in the United States to respiratory-focused physicians and key retail pharmacies with its 50 person specialty sales force. Cornerstone also generates revenue from the sale of seven marketed product lines that include products that it does not promote.

Some of Cornerstone s marketed products are approved by the FDA while others are marketed in the United States without an FDA-approved marketing application because they have been considered by Cornerstone to be identical, related or similar to products that have existed in the market without an FDA-approved marketing application, and which were thought not to require pre-market review and approval, or which were approved only on the basis of safety, at the time they entered the marketplace, subject to FDA enforcement policies established in connection with the FDA s Drug Efficacy Study Implementation, or DESI, program. For a more complete discussion regarding FDA

drug approval requirements, please see the section entitled Risks Related to Cornerstone Some of Cornerstone s specialty pharmaceutical products are now being marketed without approved NDAs or ANDAs beginning on page 70 of this proxy statement/prospectus and the section entitled Cornerstone s Business Regulatory Matters beginning on page 222 of this proxy statement/prospectus.

Table of Contents

Cornerstone derives revenues from the following products as of September 15, 2008:

| Product | Promoted by Cornerstone | Approved by FDA |
|---|---|---|
| ALLERX 10 Dose Pack and ALLERX 30 Dose Pack | Yes | No |
| ALLERX Dose Pack DF and ALLERX Dose Pack DF 30 | Yes | No |
| ALLERX Dose Pack PE and ALLERX Dose Pack PE 30 | Yes | No |
| ALLERX Suspension | No | No |
| ALLERX-D | No | No |
| APAP 325 | No | Yes |
| APAP 500 | No | Yes |
| BALACET 325 | No | Yes |
| DECONSAL CT | No | No |
| DECONSAL DM | No | No |
| Extendryl | No | No |
| HYOMAX DT | No | No |
| HYOMAX FT | No | No |
| HYOMAX SL | No | No |
| HYOMAX SR | No | No |
| RESPIVENT DF Dose Pack | No | No |
| RESPIVENT-D | No | No |
| SPECTRACEF | Yes | Yes |

Cornerstone s commercial strategy is to acquire non-promoted or underperforming branded pharmaceutical products and then maximize their potential value by promoting the products using its sales and marketing capabilities and applying various product life cycle management techniques. Cornerstone s product development pipeline consists of three line extensions of SPECTRACEF and three other product candidates for the respiratory market, which consist of the following:

| Product Candidate | Regulatory Status | Therapeutic Class | Development Stage |
|---|---|---|---|
| Spectracef Line Extensions | | | |
| SPECTRACEF 400 mg | sNDA approved in July 2008 | Antibiotic | Product launch targeted for fourth quarter of 2008 |
| SPECTRACEF Once Daily | NDA submission targeted in 2010 | Antibiotic | Phase I clinical trial targeted to begin in the fourth quarter of 2008 |
| SPECTRACEF Suspension | NDA submission for pharyngitis or tonsillitis targeted in 2009; sNDA submission for acute otitis media targeted in 2010 | Antibiotic | Phase III clinical trials completed for pharyngitis or tonsillitis indication; Phase III clinical trials for acute otitis media targeted to |

| | | | |
|---|---|---|---|
| | | | begin in 2009 |
| Other Product Candidates | | | |
| CBP 058 | NDA submission targeted in 2010 | Antihistamine and anticholinergic combination | Phase I clinical trial targeted to begin in the first quarter of 2009 |
| CBP 067 | Regulatory submission targeted in 2009 | Antihistamine and antitussive combination | Phase I clinical trial targeted to begin in 2009 |
| CBP 069 | Regulatory submission targeted in 2009 | Antihistamine and antitussive combination | Phase I clinical trial targeted to begin in 2009 |

Table of Contents

**Summary of the Merger (see page 96)**

If the merger is consummated, Cornerstone and the transitory subsidiary, a wholly owned subsidiary of Critical Therapeutics, will merge, with Cornerstone surviving as a wholly owned subsidiary of Critical Therapeutics. A copy of the merger agreement is attached as *Annex A* to this proxy statement/prospectus. You are encouraged to read the merger agreement in its entirety because it is the legal document that governs the merger.

**Reasons for the Merger (see page 108)**

Critical Therapeutics and Cornerstone believe that the combined company resulting from the merger will have the following potential advantages:

- The combined company will be a larger respiratory-focused specialty pharmaceutical company with multiple marketed products, a more balanced revenue stream and important product development opportunities.

- The combined company is expected to focus its resources on developing a successful specialty pharmaceutical business without the additional challenge of trying to simultaneously build an early-stage drug development pipeline.

- There are significant potential synergies and cost savings that Critical Therapeutics and Cornerstone believe can be achieved by consolidating the infrastructures of the two companies and allowing management to fully leverage the combined sales force across multiple revenue generating products.

Each of the boards of directors of Critical Therapeutics and Cornerstone also considered other reasons for the merger, as described herein.

Critical Therapeutics board of directors considered, among other things:

- Critical Therapeutics limited prospects if it were to remain an independent, standalone company;

- the opportunity for Critical Therapeutics stockholders to participate in the potential future value of the combined company; and

- its view as to the potential for other third parties to enter into strategic relationships with or acquire Critical Therapeutics on favorable terms, if at all, based on the lack of interest expressed by third parties during the strategic alternatives review process undertaken by Critical Therapeutics.

Cornerstone s board of directors considered, among other things:

- the opportunity to expand Cornerstone s respiratory product portfolio with ZYFLO CR;

- the view that the combination with Critical Therapeutics would result in a combined company with the potential for enhanced future growth and value as compared to Cornerstone as an independent, standalone company;

- the likely greater range of options available to the combined company to access private and public equity markets should additional capital be needed in the future than the range of options available to Cornerstone as a

private company; and

the possibility of other alternatives to expand Cornerstone s product portfolio through the acquisition of rights to FDA-approved respiratory products through asset purchase or licensing transactions not involving a strategic combination with another company.

**Opinion of Critical Therapeutics Financial Advisor (see page 113)**

In connection with the merger, Critical Therapeutics board of directors received an opinion, dated May 1, 2008, from Critical Therapeutics financial advisor, Lazard Frères & Co. LLC, or Lazard, as to the fairness, from a financial point of view and as of the date of such opinion, to Critical Therapeutics of the exchange ratio provided for in the merger. The full text of Lazard s opinion, which sets forth, among other things, the procedures followed, assumptions made, matters considered and qualifications and limitations on the review

Table of Contents

undertaken by Lazard in connection with its opinion, is attached to this proxy statement/prospectus as *Annex D* and is incorporated by reference into this proxy statement/prospectus. **Lazard s opinion was addressed to Critical Therapeutics board of directors, was only one of many factors considered by Critical Therapeutics board of directors in its evaluation of the merger and only addresses the fairness of the exchange ratio from a financial point of view to Critical Therapeutics. Lazard s opinion does not address the merits of the underlying decision by Critical Therapeutics to engage in the merger or related transactions or the relative merits of the merger or related transactions as compared to any other transaction or business strategy in which Critical Therapeutics might engage, and is not intended to, and does not, constitute a recommendation to any stockholder as to how such stockholder should vote or act with respect to the merger or any matter relating to the merger.**

**Overview of the Merger Agreement**

***Merger Consideration (see page 137)***

At the effective time of the merger, each share of Cornerstone s common stock will be converted into and exchanged for the right to receive a number of shares of Critical Therapeutics common stock equal to the product of 2.3333 multiplied by the quotient of 43,479,198, which was the number of outstanding shares of Critical Therapeutics common stock on April 30, 2008, divided by the number of shares of Cornerstone s common stock outstanding immediately prior to the effective time of the merger, assuming the exercise or conversion of all outstanding Cornerstone stock options and warrants, subject to adjustment for the reverse stock split of Critical Therapeutics common stock. The exact exchange ratio per share of Cornerstone s common stock will be based in part on the number of shares of Cornerstone s common stock outstanding or issuable pursuant to outstanding options and warrants immediately prior to the effective time of the merger and will not be calculated until that time.

***Conditions to Completion of the Merger (see page 138)***

Consummation of the merger is subject to a number of conditions, including among others, subject to specified exceptions, the following:

- the approval by Critical Therapeutics stockholders of the issuance of Critical Therapeutics common stock in the merger, the reverse stock split and the name change to Cornerstone Therapeutics Inc. ;
- the effectiveness of Critical Therapeutics registration statement on Form S-4, of which this proxy statement/prospectus forms a part, with no stop order initiated, pending or threatened by the SEC;
- the absence of any order, preliminary or permanent injunction or statute, rule or regulation of any court or other governmental or regulatory authority prohibiting consummation of the merger;
- the approval by The NASDAQ Stock Market LLC, or NASDAQ, of the re-listing of Critical Therapeutics common stock on The NASDAQ Capital Market pursuant to NASDAQ s reverse merger rules and the initial listing of Critical Therapeutics common stock issuable in connection with the merger or upon exercise of Cornerstone s outstanding stock options or warrants;
- the continued commercial availability of Critical Therapeutics products, ZYFLO CR or ZYFLO;
- the exchange or conversion of the outstanding principal amount of that certain Promissory Note, dated April 19, 2004, as amended, or the Carolina Note, issued by a wholly owned subsidiary of Cornerstone, into shares of Cornerstone s common stock;

the exercise of appraisal rights by holders of not more than 5% of Cornerstone s outstanding common stock; and

the absence of any material adverse change, event, circumstance or development with respect to, or material adverse effect on, the business, assets, liabilities, condition (financial or other) or results of operations of either Critical Therapeutics or Cornerstone.

Table of Contents

***No Solicitation (see page 140)***

Each of Cornerstone and Critical Therapeutics agreed that, subject to specified exceptions, Cornerstone and Critical Therapeutics will not, nor will either of them authorize or permit any of their or their respective subsidiaries subsidiaries or any of their or their subsidiaries respective officers, directors, investment bankers, attorneys, accountants or other advisors or representatives to, directly or indirectly:

solicit, initiate, encourage or take any other action designed to facilitate any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, any acquisition proposal, as defined in the merger agreement and explained in this proxy statement/prospectus; or

enter into, continue or otherwise participate in any discussions or negotiations regarding, furnish to any person any information with respect to, assist or participate in any effort or attempt by any person with respect to, or otherwise cooperate in any way with, any acquisition proposal.

***Termination of the Merger Agreement (see page 147)***

The merger agreement may be terminated at any time before the completion of the merger:

by mutual written consent of Cornerstone and Critical Therapeutics;

by either Cornerstone or Critical Therapeutics if the merger has not been completed by November 30, 2008, unless the failure to complete the merger is due to the terminating party s failure to fulfill any obligation under the merger agreement;

by either Cornerstone or Critical Therapeutics if the merger is permanently restrained, enjoined or otherwise prohibited by a governmental entity;

by either Cornerstone or Critical Therapeutics if Critical Therapeutics stockholders do not approve the proposals presented at the special meeting, unless:

the party seeking to terminate is in breach of or has failed to fulfill its obligations under the merger agreement, or

Critical Therapeutics is seeking to terminate and has failed to obtain the requisite vote due to a breach by any party other than Cornerstone of the stockholder agreements entered into with Critical Therapeutics stockholders in connection with the merger;

by Critical Therapeutics if:

Cornerstone s board of directors fails to make, withdraws or modifies its recommendation that Cornerstone s stockholders vote to approve the merger agreement and the merger,

after the receipt by Cornerstone of an acquisition proposal, Cornerstone s board of directors fails to reconfirm its recommendation of the merger agreement or the merger,

Cornerstone s board of directors approves or recommends any acquisition proposal,

a tender or exchange offer for Cornerstone s common stock is commenced and Cornerstone s board of directors recommends that Cornerstone s stockholders tender their shares in such offer or fails to recommend against acceptance of such offer, or

Cornerstone breaches its non-solicitation obligations;

by Cornerstone if:

Critical Therapeutics board of directors fails to make, withdraws or modifies its recommendation that Critical Therapeutics stockholders vote for the proposals presented at the special meeting,

after the receipt by Critical Therapeutics of an acquisition proposal, Critical Therapeutics board of directors fails to reconfirm its recommendation of the merger agreement or the merger,

Critical Therapeutics board of directors approves or recommends any acquisition proposal,

Table of Contents

a tender or exchange offer for Critical Therapeutics common stock is commenced (other than by Cornerstone or its affiliates) and Critical Therapeutics board of directors recommends that Critical Therapeutics stockholders tender their shares in such offer or fails to recommend against acceptance of such offer,

Critical Therapeutics breaches its non-solicitation obligations or stockholder covenants, or

Critical Therapeutics fails to hold the special meeting by November 28, 2008; or

by either Cornerstone or Critical Therapeutics if there has been a breach of or failure to perform any representation, warranty, covenant or agreement by the other party that would cause conditions to the closing of the merger not to be satisfied, and such failure or breach is not cured within 30 days after receipt of written notice from the non-breaching party, provided that such 30 day period may not extend beyond November 26, 2008.

***Termination Fees and Expenses (see page 148)***

The merger agreement provides for the payment of a termination fee of $1.0 million by each of Critical Therapeutics and Cornerstone to the other party in specified circumstances in connection with the termination of the merger agreement. In addition, in specified circumstances in connection with termination of the merger agreement, Critical Therapeutics has agreed to reimburse Cornerstone for up to $150,000 in expenses, and Cornerstone has agreed to reimburse Critical Therapeutics for up to $100,000 in expenses.

**Stockholder Agreements and Noteholder Agreement (see page 151)**

In connection with the execution of the merger agreement, holders of approximately 81% of the shares of Cornerstone s outstanding common stock have entered into agreements with Critical Therapeutics that provide, among other things, that the stockholders will vote in favor of adoption of the merger agreement and grant to Critical Therapeutics an irrevocable proxy to vote all of such stockholders shares of Cornerstone common stock in favor of adoption of the merger agreement and against any proposal made in opposition to, or in competition with, the proposal to adopt the merger agreement. In addition, these Cornerstone stockholders have agreed not to transfer or otherwise dispose of any shares of Critical Therapeutics common stock that they receive in the merger for 180 days after the effective time of the merger. Furthermore, Carolina Pharmaceuticals Ltd., or Carolina Pharmaceuticals, which is the holder of the Carolina Note, has entered into an agreement that provides, among other things, for the exchange or conversion of the outstanding principal amount of the Carolina Note into approximately 18% of the shares of Cornerstone s common stock outstanding immediately prior to the effective time of the merger and for the same voting and lock-up provisions provided for pursuant to the agreements that Cornerstone s other stockholders have entered into.

In connection with the execution of the merger agreement, funds managed by Healthcare Ventures and Advanced Technology Ventures, which, as of May 1, 2008, owned in the aggregate approximately 19% of Critical Therapeutics outstanding common stock, have entered into agreements with Cornerstone that provide, among other things, that the stockholders will vote in favor of the issuance of shares of Critical Therapeutics common stock in the merger and grant to Cornerstone an irrevocable proxy to vote such stockholders shares of Critical Therapeutics common stock in favor of the issuance of Critical Therapeutics common stock in the merger and against any proposal made in opposition to, or in competition with, the issuance of shares of Critical Therapeutics common stock in the merger.

Table of Contents

**Management Following the Merger (see page 294)**

Promptly following the effective time of the merger, the executive management team of the combined company is expected to be composed primarily of current Cornerstone executives, including the following individuals:

| Name | Position with the Combined Company | Current Position |
|---|---|---|
| Craig A. Collard | President and Chief Executive Officer | Cornerstone s President and Chief Executive Officer |
| Chenyqua Baldwin | Vice President, Finance, Chief Accounting Officer and Controller | Cornerstone s Vice President, Finance |
| Brian Dickson, M.D. | Chief Medical Officer | Cornerstone s Chief Medical Officer |
| George Esgro | Vice President, Sales and Marketing | Cornerstone s Vice President, Sales and Marketing |
| Steven M. Lutz | Executive Vice President, Manufacturing and Trade | Cornerstone s Executive Vice President, Commercial Operations |
| David Price | Executive Vice President, Finance, and Chief Financial Officer | Cornerstone s Executive Vice President, Finance, and Chief Financial Officer |

In addition, Scott B. Townsend, Critical Therapeutics General Counsel, Senior Vice President of Legal Affairs and Secretary, is expected to serve as General Counsel, Executive Vice President of Legal Affairs and Secretary of the combined company.

**The Board of Directors Following the Merger (see page 297)**

Pursuant to the merger agreement, promptly following the effective time of the merger, Critical Therapeutics has agreed to take all necessary actions to appoint Craig A. Collard, Cornerstone s President and Chief Executive Officer and a member of Cornerstone s board of directors, and Alastair McEwan, the Chairman of Cornerstone s board of directors, to Critical Therapeutics board of directors. In addition, Critical Therapeutics has agreed to take all necessary actions to obtain the resignations of its current directors. Contemporaneously with the resignation of Critical Therapeutics current directors and the appointment of Craig A. Collard and Alastair McEwan to Critical Therapeutics board of directors, the size of Critical Therapeutics board of directors will be fixed at five directors and Christopher Codeanne, Michael Enright and Michael Heffernan will be appointed to fill the other vacancies on Critical Therapeutics board of directors, provided that such directors are independent under applicable NASDAQ requirements or SEC regulations. Following the effective time of the merger, Critical Therapeutics board of directors will remain divided into three classes, with one class being elected each year and members of each class holding office for a three-year term. Based on the foregoing, the members of each class of Critical Therapeutics board of directors will be as follows: Class I Director (term to expire at the 2011 annual meeting of stockholders): Craig A. Collard; Class II Directors (terms to expire at the 2009 annual meeting of stockholders): Christopher Codeanne and Michael Enright; and Class III Directors (terms to expire at the 2010 annual meeting of stockholders): Alastair McEwan and Michael Heffernan.

**Interests of Critical Therapeutics Directors and Executive Officers (see page 119)**

In considering the recommendation of Critical Therapeutics board of directors with respect to issuing shares of Critical Therapeutics common stock pursuant to the merger agreement and the other matters to be acted upon by Critical Therapeutics stockholders at the special meeting, Critical Therapeutics stockholders should be aware that members of the board of directors and executive officers of Critical Therapeutics have interests in the merger that may be different from, or in addition to, interests they may have as Critical Therapeutics stockholders.

Table of Contents

For example, pursuant to the terms of employment agreements with Critical Therapeutics executive officers and a change of control cash bonus program established by Critical Therapeutics, upon the consummation of the merger, the executive officers of Critical Therapeutics are entitled to receive aggregate cash payments of approximately $305,000 and accelerated vesting of restricted stock with an aggregate value of approximately $16,978, assuming that the merger had been consummated on September 15, 2008. Assuming each executive officer of Critical Therapeutics is terminated other than for cause or terminates his employment for good reason, in each case as those terms are defined in his employment agreement, within specified periods before or after the consummation of the merger, then the executive officers of Critical Therapeutics would be entitled to receive aggregate cash payments of approximately $1,814,318, accelerated vesting of restricted stock with an aggregate value of approximately $33,956 and additional aggregate payments of approximately $88,150 for COBRA premiums for continued health and dental coverage, premiums for life insurance and disability insurance and outplacement services, assuming that the merger had been consummated on September 15, 2008. Although the executive officers and directors of Critical Therapeutics are entitled to accelerated vesting of unvested stock options in connection with the merger, all stock options subject to accelerated vesting have an exercise price that is greater than $0.22 per share, the closing market price of Critical Therapeutics common stock on September 15, 2008. Unvested stock options held by executive officers and directors of Critical Therapeutics that are subject to accelerated vesting have exercise prices ranging from $1.05 to $8.58 per share and a weighted average exercise price of $3.32 per share. Following the effective time of the merger, the executive management team of the combined company is expected to be composed primarily of current Cornerstone executives. It is not expected that any of the current executive officers or directors of Critical Therapeutics will continue his or her service with the combined company following the merger, other than Scott B. Townsend, Critical Therapeutics General Counsel, Senior Vice President of Legal Affairs and Secretary.

In anticipation of Mr. Townsend s service to the combined company following the merger, on September 16, 2008, Critical Therapeutics entered into an amendment to the amended and restated employment agreement between Critical Therapeutics and Mr. Townsend. This amendment will be effective from the effective time of the merger to December 31, 2010 and will only become effective if the merger is consummated. Under the terms of this amendment, Mr. Townsend will serve as the General Counsel, Executive Vice President of Legal Affairs and Secretary of the combined company. The amendment provides for an increase in Mr. Townsend s annual target cash bonus as a percentage of base salary from 30% to 35% and an actual annual cash bonus for Mr. Townsend for 2008 of not less than 35% of his base salary if he remains an employee in good standing through December 31, 2008. Mr. Townsend will continue to receive an annual base salary of $275,000. In connection with such amendment, Critical Therapeutics also entered into a restricted stock agreement with Mr. Townsend that provides for a restricted stock grant to Mr. Townsend on the first business day after the consummation of the merger of a number of shares of common stock representing one percent of the combined company s outstanding equity, on a fully diluted basis but excluding an aggregate of 7,208,707 shares of Critical Therapeutics common stock underlying warrants issued in connection with a June 2005 private placement and an October 2006 registered offering, after giving effect to the reverse stock split and the merger, subject to the terms of such restricted stock agreement. The restricted stock agreement will only become effective if the merger is consummated. It is expected that approximately 1,489,789 shares will be issued to Mr. Townsend pursuant to the restricted stock agreement, subject to adjustment as a result of the reverse stock split. The amendment to Mr. Townsend s amended and restated employment agreement also provides for additional potential future benefits to Mr. Townsend in connection with a termination of his employment by the combined company other than for cause or by Mr. Townsend for good reason.

Assuming that the merger had been consummated on September 15, 2008, the beneficial ownership and other equity interests of Mr. Townsend in the combined company immediately following the merger are expected to be as set forth below:

| Name | Total Shares Beneficially Owned | Total Options Held | Options Exercisable Within 60 Days | Company Beneficial Ownership Percentage |
|---|---|---|---|---|
| Scott B. Townsend | 1,751,672 | 244,000 | 167,015 | 1.4% |

Table of Contents

As of September 15, 2008, all directors and executive officers of Critical Therapeutics, together with their affiliates, beneficially owned approximately 23.2% of the shares of Critical Therapeutics common stock. The affirmative vote of the holders of a majority of the shares of Critical Therapeutics common stock present in person or represented by proxy and voting on such matter at the special meeting is required for approval of Proposal 1 and Proposal 4. The affirmative vote of holders of a majority of the outstanding shares of Critical Therapeutics common stock as of the record date for the special meeting is required for approval of Proposal 2 and Proposal 3.

**Interests of Cornerstone s Directors and Executive Officers (see page 125)**

Critical Therapeutics stockholders also should be aware that members of the board of directors and executive officers of Cornerstone have interests in the merger that may be different from, or in addition to, interests they may have as Cornerstone stockholders.

Cornerstone s executive officers are expected to continue as executive officers of the combined company with initial annual base salaries following the merger that are identical to their respective annual base salaries with Cornerstone immediately prior to the merger. These individuals, their expected positions and annual base salaries with the combined company are as follows:

Craig A. Collard, President and Chief Executive Officer, annual base salary of $379,600;

Chenyqua Baldwin, Vice President, Finance, Chief Accounting Officer and Controller, annual base salary of $223,600;

Brian Dickson, M.D., Chief Medical Officer, annual base salary of $270,400;

George Esgro, Vice President, Sales and Marketing, annual base salary of $220,000;

Steven M. Lutz, Executive Vice President, Manufacturing and Trade, annual base salary of $250,000; and

David Price, Executive Vice President, Finance, and Chief Financial Officer, annual base salary of $285,000.

As of May 2, 2008, the date that holders of a majority of the shares of Cornerstone s outstanding common stock acting by written consent without a meeting in accordance with Section 228 of the Delaware General Corporation Law and Cornerstone s bylaws approved the merger agreement and the transactions contemplated thereby, Mr. Collard controlled, directly or indirectly, 54% of the outstanding shares of Cornerstone s common stock, and Cornerstone s executive officers and directors, and their affiliates, in the aggregate controlled, directly or indirectly, 68.3% of the outstanding shares of Cornerstone s common stock.

Assuming that the merger had been consummated on September 15, 2008, Cornerstone s executive officers and directors, and their affiliates, would beneficially own, in the aggregate, approximately 51% of the outstanding common stock of the combined company, including any shares of the common stock of the combined company issuable in the merger in exchange for shares of Cornerstone s outstanding common stock to be issued to Carolina Pharmaceuticals upon the exchange or conversion prior to the merger of the outstanding principal amount under the Carolina Note into shares of Cornerstone s common stock pursuant to the noteholder agreement between Carolina Pharmaceuticals and Critical Therapeutics. Additionally, Cornerstone s executive officers and directors would hold certain options to acquire shares of the common stock of the combined company that are not considered beneficially owned because such options are not exercisable within sixty days of September 15, 2008. Assuming that the merger had been consummated on September 15, 2008 and assuming an exchange ratio of

9

Table of Contents

2.448566, the beneficial ownership and other equity interests of Cornerstone s executive officers and directors, and their affiliates, in the combined company immediately following the merger are expected to be as set forth below:

| Name | Total Shares Beneficially Owned | Total Options Held | Options Exercisable Within 60 Days | Combined Company Beneficial Ownership Percentage |
|---|---|---|---|---|
| Craig A. Collard(1) | 48,091,789 | 2,569,839 | 734,239 | 38.2% |
| Chenyqua Baldwin | 2,429,109 | 2,055,871 | 593,510 | 1.9 |
| Brian Dickson, M.D. | 1,636,742 | 3,671,199 | 1,636,742 | 1.3 |
| George Esgro(2) | | 734,239 | | |
| Steven M. Lutz | 7,651,389 | 2,263,906 | 688,349 | 6.1 |
| Alastair McEwan | 2,753,399 | 3,671,199 | 2,753,399 | 2.2 |
| David Price(3) | 3,186,052 | | | 2.5 |

(1) Total shares beneficially owned consists of 32,933,206 shares of common stock held by Cornerstone BioPharma Holdings, Ltd., 14,439,134 shares of common stock held by Carolina Pharmaceuticals received in connection with the conversion of the outstanding principal amount under the Carolina Note and options to purchase 734,569 shares of common stock pursuant to stock option grants awarded to Mr. Collard under Cornerstone s 2005 Stock Incentive Plan. Mr. Collard is the controlling shareholder and a director of Cornerstone Biopharma Holdings, Ltd. and by virtue of such positions will exercise voting and investment power with respect to the shares of the combined company to be owned by Cornerstone Biopharma Holdings, Ltd. following the merger. Mr. Collard is the chief executive officer and chairman of the board of Carolina Pharmaceuticals and by virtue of such positions will exercise voting and investment power with respect to the shares of the combined company to be owned by Carolina Pharmaceuticals following the merger.

(2) Pursuant to the Employment Agreement, dated March 3, 2008, between Cornerstone and Mr. Esgro, Cornerstone is obligated to grant Mr. Esgro an option to purchase 300,000 shares of Cornerstone s common stock. Cornerstone expects that the option award to Mr. Esgro will be completed immediately prior to the effective time of the merger.

(3) Mr. Price became the Executive Vice President, Finance, and Chief Financial Officer of Cornerstone effective as of September 8, 2008. Pursuant to the Executive Employment Agreement, dated August 20, 2008, between Cornerstone and Mr. Price, Cornerstone is obligated to issue to Mr. Price 1,301,776 restricted shares of Cornerstone common stock. Cornerstone expects that this restricted stock award to Mr. Price will be completed immediately prior to the effective time of the merger. In connection with the merger, Mr. Price s 1,301,776 restricted shares of Cornerstone common stock will be converted into restricted shares of the combined company s common stock.

Carolina Pharmaceuticals, which is the holder of the Carolina Note, has entered into an agreement with Critical Therapeutics that provides, among other things, for the exchange or conversion prior to the merger of the outstanding principal amount of the Carolina Note into shares of Cornerstone s common stock. Mr. Collard is the Chief Executive Officer and Chairman of the Board of Carolina Pharmaceuticals. In addition, Ms. Baldwin and Mr. Lutz are directors of Carolina Pharmaceuticals. As of September 15, 2008, the outstanding principal amount of the Carolina Note was approximately $9.0 million, which assuming an exchange ratio of 2.448566 would be converted into approximately

14,439,134 shares, or 11.5%, of the combined company s outstanding common stock immediately following the consummation of the merger.

**Stock Options and Warrants (see page 128)**

Each outstanding option to purchase shares of Cornerstone common stock, whether vested or unvested, and all stock option plans or other stock or equity-related plans of Cornerstone themselves, insofar as they relate to outstanding Cornerstone s stock options, will be assumed by Critical Therapeutics and will become an option to acquire, on the same terms and conditions as were applicable under such Cornerstone s stock option immediately prior to the effective time of the merger, such number of shares of Critical Therapeutics common stock as is equal to the number of shares of Cornerstone s common stock subject to the unexercised portion of such Cornerstone stock option immediately prior to the effective time of the merger multiplied by the exchange ratio

Table of Contents

(rounded down to the nearest whole share number), at an exercise price per share equal to the exercise price per share of such Cornerstone stock option immediately prior to the effective time of the merger divided by the exchange ratio (rounded up to the nearest whole cent). To the extent not exercised prior to the consummation of the merger, Cornerstone anticipates that there will be approximately 7,960,621 shares of Cornerstone s common stock underlying outstanding stock options immediately prior to the effective time of the merger.

Each warrant to purchase shares of Cornerstone common stock outstanding immediately prior to the effective time of the merger will be assumed by Critical Therapeutics and will become a warrant to acquire, on the same terms and conditions as were applicable under such warrant, such number of shares of Critical Therapeutics common stock as is equal to the number of shares of Cornerstone s common stock subject to the unexercised portion of such Cornerstone warrant immediately prior to the effective time of the merger multiplied by the exchange ratio (rounded down to the nearest whole share number), at an exercise price per share equal to the exercise price per share of such Cornerstone warrant immediately prior to the effective time of the merger divided by the exchange ratio (rounded up to the nearest whole cent). Cornerstone anticipates that warrants to purchase an aggregate of 1,326,903 shares of Cornerstone s common stock underlying warrants outstanding as of September 15, 2008 will be exercised prior to the effective time of the merger. Following such exercises, Cornerstone anticipates that there will be 20,000 shares of Cornerstone s common stock underlying outstanding warrants immediately prior to the effective time of the merger.

As of the effective time of the reverse stock split, Critical Therapeutics will adjust and proportionately decrease the number of shares of Critical Therapeutics common stock reserved for issuance upon exercise of, and adjust and proportionately increase the exercise price of, all options and warrants to acquire Critical Therapeutics common stock. In addition, as of the effective time of the reverse stock split, Critical Therapeutics will adjust and proportionately decrease the total number of shares of Critical Therapeutics common stock that may be the subject of future grants under Critical Therapeutics stock option plans. All stock options and warrants to acquire shares of Critical Therapeutics common stock that are outstanding immediately prior to the effective time of the merger will remain outstanding following the effective time of the merger.

**Material U.S. Federal Income Tax Consequences of the Merger (see page 130)**

The merger has been structured to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended, or the Code, and it is a closing condition to the merger that Critical Therapeutics and Cornerstone receive opinions of their respective counsel regarding such qualification. There will be no U.S. federal income tax consequences to Critical Therapeutics stockholders as a result of the merger. As a result of the merger s qualification as a reorganization, Cornerstone s stockholders will not recognize gain or loss for U.S. federal income tax purposes upon the exchange of shares of Cornerstone s common stock for shares of Critical Therapeutics common stock, except with respect to cash received in lieu of fractional shares of Critical Therapeutics common stock.

Tax matters are very complicated, and the tax consequences of the merger to a particular stockholder will depend in part on such stockholder s circumstances. Accordingly, you are urged to consult your own tax advisor for a full understanding of the tax consequences of the merger to you, including the applicability and effect of federal, state, local and foreign income and other tax laws.

**Risk Factors (see page 24)**

Both Critical Therapeutics and Cornerstone are subject to various risks associated with their businesses and their industries, and the combined business will also be subject to those and other risks. In addition, the merger poses a number of risks to each company and its stockholders, including the following risks:

Some of Critical Therapeutics and Cornerstone s officers and directors have interests in the merger that may be different from yours and influence them to support or approve the merger.

The merger may be completed even though material adverse changes may result from the announcement of the merger, industry-wide changes and other causes.

The market price of Critical Therapeutics common stock has fallen significantly since the public announcement of the proposed merger. If the merger is completed and the perceived benefits of the merger are not realized, the market price of the combined company may decline further.

Table of Contents

Critical Therapeutics and Cornerstone s stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger.

Negative perceptions regarding the pending merger may harm either Critical Therapeutics or Cornerstone s business and employee relationships.

**Regulatory Approvals (see page 130)**

Neither Critical Therapeutics nor Cornerstone is required to make any filings or to obtain approvals or clearances from any antitrust regulatory authorities in the United States or other countries to consummate the merger. In the United States, Critical Therapeutics must comply with applicable federal and state securities laws and NASDAQ rules and regulations in connection with the issuance of shares of Critical Therapeutics common stock in the merger, including the filing with the SEC of this proxy statement/prospectus. As of the date hereof, the registration statement has not become effective. Critical Therapeutics has filed an initial listing application with The NASDAQ Capital Market pursuant to NASDAQ s reverse merger rules for the re-listing of Critical Therapeutics common stock in connection with the merger and to effect the initial listing of Critical Therapeutics common stock issuable in connection with the merger or upon exercise of Cornerstone s outstanding stock options or warrants.

**Anticipated Accounting Treatment (see page 134)**

The merger will be treated by Critical Therapeutics as a reverse merger under the purchase method of accounting in accordance with U.S. generally accepted accounting principles, or GAAP. For accounting purposes, Cornerstone is considered to be acquiring Critical Therapeutics in this transaction.

**Appraisal Rights (see page 134)**

Critical Therapeutics stockholders are not entitled to appraisal rights in connection with the merger or any of the proposals to be voted on at the special meeting.

Cornerstone s stockholders are entitled to appraisal rights if they did not vote in favor of the merger agreement and they comply with the conditions established by Section 262 of the Delaware General Corporation Law.

It is a condition to the obligation of Critical Therapeutics and the transitory subsidiary to complete the merger that holders of not more than 5% of Cornerstone s outstanding common stock exercise appraisal rights.

**Comparison of Stockholder Rights (see page 339)**

Both Critical Therapeutics and Cornerstone are incorporated under the laws of the State of Delaware and, accordingly, the rights of the stockholders of each are currently, and will continue to be, governed by the Delaware General Corporation Law. If the merger is completed, Cornerstone s stockholders will become stockholders of Critical Therapeutics, and their rights will be governed by the Delaware General Corporation Law, the certificate of incorporation of Critical Therapeutics and the bylaws of Critical Therapeutics. The rights of Critical Therapeutics stockholders contained in the certificate of incorporation and bylaws of Critical Therapeutics differ from the rights of Cornerstone s stockholders under the certificate of incorporation and bylaws of Cornerstone.

**Legal Proceedings (see page 189)**

On September 17, 2008, a purported shareholder class action lawsuit was filed by a single plaintiff against Critical Therapeutics and each of its directors in the Court of Chancery of The State of Delaware. The complaint alleges, among other things, that the defendants breached fiduciary duties of loyalty and good faith, including a fiduciary duty of candor, by failing to provide Critical Therapeutics stockholders with a proxy statement/prospectus adequate to enable them to cast an informed vote on the proposed merger, and by possibly failing to maximize stockholder value by entering into an agreement that effectively discourages competing offers. The complaint seeks, among other things, an order (i) enjoining the defendants from proceeding with or implementing the proposed merger on the terms and under the circumstances as they presently exist, (ii) invalidating the provisions of the proposed merger that purportedly improperly limit the effective exercise of the defendants continuing fiduciary duties; (iii) ordering defendants to explore alternatives and to negotiate in good faith with all *bona fide* interested parties; (iv) in the event the proposed merger is consummated, rescinding it and setting it aside or awarding rescissory damages; (v) awarding compensatory damages against defendants, jointly and severally; and (vi) awarding the plaintiff and the purported class their costs and fees.

Table of Contents

## SELECTED HISTORICAL AND PRO FORMA COMBINED FINANCIAL DATA

The following tables present summary historical financial data for Critical Therapeutics and Cornerstone, summary unaudited pro forma condensed combined financial data for Critical Therapeutics and Cornerstone, and comparative historical and unaudited pro forma per share data for Critical Therapeutics and Cornerstone.

Table of Contents

**Selected Historical Consolidated Financial Data of Critical Therapeutics**

The statements of operations data for the years ended December 31, 2007, 2006 and 2005 and the balance sheet data as of December 31, 2007 and 2006 are derived from Critical Therapeutics audited consolidated financial statements, which are included in this proxy statement/prospectus beginning on page F-3. The statements of operations data for the six months ended June 30, 2008 and 2007 and the balance sheet data as of June 30, 2008 and 2007 are derived from Critical Therapeutics unaudited consolidated financial statements, which are included in this proxy statement/prospectus beginning on page F-36. The statements of operations data for the years ended December 31, 2004 and 2003 and the balance sheet data as of December 31, 2005, 2004 and 2003 are derived from Critical Therapeutics audited consolidated financial statements, which are not included in this proxy statement/prospectus. Historical results are not necessarily indicative of future results and results for any interim period are not necessarily indicative of results to be expected for a full fiscal year. You should read the notes to Critical Therapeutics consolidated financial statements for an explanation of the method used to determine the number of shares used in computing basic and diluted net loss per share.

Effective January 1, 2006, Critical Therapeutics adopted SFAS 123(R), using the modified prospective method, which requires Critical Therapeutics to recognize compensation cost for granted, but unvested, awards, new awards and awards modified, repurchased, or cancelled after January 1, 2006 and granted after Critical Therapeutics became a public company. The amounts for prior periods do not include the impact of SFAS 123(R). In the notes to Critical Therapeutics consolidated financial statements, Critical Therapeutics has provided pro forma disclosures for the year ended December 31, 2005 in accordance with SFAS 123 since that period has not been retroactively adjusted to reflect the SFAS 123 pro forma amounts in the prior period financial statements.

| | Six Months Ended | | Year Ended December 31, | | | | |
|---|---|---|---|---|---|---|---|
| | June 30, 2008 | June 30, 2007 | 2007 | 2006 | 2005 | 2004 | 2003 |
| | (In thousands, except share and per share data) | | | | | | |
| **tements of perations Data:** | | | | | | | |
| t product sales | $ 7,227 | $ 5,185 | $ 11,008 | $ 6,647 | $ 387 | $ | $ |
| venue under llaboration and ense agreements | | 1,737 | 1,861 | 6,431 | 5,837 | 4,436 | 1,02 |
| tal revenues | 7,227 | 6,922 | 12,869 | 13,078 | 6,224 | 4,436 | 1,02 |
| st of products sold | 4,657 | 1,421 | 4,233 | 2,222 | 514 | | |
| search and velopment | 6,927 | 13,022 | 21,655 | 26,912 | 29,959 | 25,578 | 17,45 |
| es and marketing | 6,031 | 4,582 | 12,193 | 18,284 | 13,671 | 1,199 | |
| neral and ministrative | 6,010 | 6,588 | 13,572 | 13,456 | 11,406 | 9,679 | 3,77 |
| structuring charges | 1,204 | | | 3,498 | | | |
| | 24,829 | 25,613 | 51,653 | 64,372 | 55,550 | 36,456 | 21,22 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| tal costs and penses | | | | | | | |
| erating loss | (17,602) | (18,691) | (38,784) | (51,294) | (49,326) | (32,020) | (20,20 |
| erest income | 289 | 1,154 | 2,020 | 2,726 | 2,427 | 1,098 | 19 |
| erest expense | (85) | (69) | (209) | (214) | (191) | (172) | (9 |
| t loss | (17,398) | (17,606) | (36,973) | (48,782) | (47,090) | (31,094) | (20,11 |
| cretion of dividends d offering costs on eferred stock | | | | | | (2,209) | (2,26 |
| t loss available to mmon stockholders | $ (17,398) | $ (17,606) | $ (36,973) | $ (48,782) | $ (47,090) | $ (33,303) | $ (22,37 |
| t loss per common are: | | | | | | | |
| sic and diluted | $ (0.41) | $ (0.41) | $ (0.87) | $ (1.37) | $ (1.61) | $ (2.28) | $ (33.9 |
| eighted-average sic and diluted ares outstanding | 42,857,558 | 42,513,852 | 42,580,884 | 35,529,048 | 29,276,243 | 14,631,371 | 658,20 |

Table of Contents

| | June 30, | | December 31, | | | | |
|---|---|---|---|---|---|---|---|
| | 2008 | 2007 | 2007 | 2006 | 2005 | 2004 | 2003 |
| | (In thousands) | | | | | | |
| **Balance Sheet Data:** | | | | | | | |
| Cash and cash equivalents | $ 10,952 | $ 39,813 | $ 33,828 | $ 48,388 | $ 57,257 | $ 11,980 | $ 40,078 |
| Short-term investments | | 650 | | 650 | 25,554 | 66,849 | |
| Working capital | 9,410 | 34,042 | 26,380 | 47,738 | 70,005 | 64,357 | 25,218 |
| Total assets | 23,358 | 50,508 | 44,924 | 58,182 | 91,819 | 83,114 | 45,054 |
| Long-term debt, net of current portion | | 122 | | 421 | 1,489 | 1,367 | 720 |
| Redeemable convertible preferred stock | | | | | | | 51,395 |
| Accumulated deficit | (208,770) | (172,005) | (191,372) | (154,399) | (105,617) | (58,527) | (27,433) |
| Total stockholders equity (deficit) | 1,176 | 34,637 | 17,091 | 49,906 | 72,247 | 65,408 | (24,851) |

Table of Contents

**Selected Historical Consolidated Financial Data of Cornerstone**

The statements of operations data for the years ended December 31, 2007, 2006 and 2005 and the balance sheet data as of December 31, 2007 and 2006 are derived from Cornerstone s audited consolidated financial statements, which are included in this proxy statement/prospectus beginning on page F-54. The statements of operations data for the six months ended June 30, 2008 and 2007 and the balance sheet data as of June 30, 2008 and 2007 are derived from Cornerstone s unaudited consolidated financial statements, which are included in this proxy statement/prospectus beginning on page F-88. The statement of operations data for the period March 30, 2004 (date of inception) through December 31, 2004 and the balance sheet data as of December 31, 2005 and 2004 are derived from Cornerstone s audited consolidated financial statements, which are not included in this proxy statement/prospectus. Historical results are not necessarily indicative of future results and results for any interim period are not necessarily indicative of results to be expected for a full fiscal year. You should read the notes to Cornerstone s consolidated financial statements for an explanation of the method used to determine the number of shares used in computing basic and diluted net loss per share.

Effective January 1, 2006, Cornerstone adopted SFAS 123(R), using the prospective method, which requires Cornerstone to recognize compensation cost for new awards and awards modified, repurchased or cancelled on or after January 1, 2006. The amounts for prior periods do not include the impact of SFAS 123(R). In the notes to Cornerstone s consolidated financial statements, Cornerstone has provided pro forma disclosures for the year ended December 31, 2005 in accordance with SFAS 123 since that period has not been restated to conform to the 2007 and 2006 presentation.

| | Six Months Ended | | Year Ended December 31, | | | March 30, 2004 (Inception) through December 31, |
|---|---|---|---|---|---|---|
| | June 30, 2008 | June 30, 2007 | 2007 | 2006 | 2005 | 2004 |
| | (In thousands, except share and per share data) | | | | | |
| **Statements of Operations Data:** | | | | | | |
| Net revenues | $ 23,512 | $ 14,203 | $ 28,071 | $ 22,117 | $ 17,470 | $ 5,740 |
| Costs and expenses: | | | | | | |
| Cost of product sales | 1,498 | 1,516 | 3,300 | 2,151 | 3,437 | 2,076 |
| Sales and marketing | 7,534 | 4,852 | 10,391 | 7,120 | 13,889 | 2,867 |
| Royalties | 4,804 | 1,631 | 3,409 | 1,663 | 1,933 | 689 |
| General and administrative | 3,773 | 2,078 | 4,106 | 3,679 | 4,881 | 1,020 |
| Research and development | 605 | 113 | 948 | 249 | 266 | |
| Amortization and depreciation | 886 | 1,686 | 3,231 | 2,704 | 1,939 | 8 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Other charges | 27 | 131 | 245 | 3,581 | 1,000 | |
| Total costs and expenses | 19,127 | 12,007 | 25,630 | 21,147 | 27,345 | 6,660 |
| Operating income (loss) | 4,385 | 2,196 | 2,441 | 970 | (9,875) | (920) |
| Other expenses: | | | | | | |
| Interest expense, net | (722) | (657) | (1,410) | (1,240) | (1,557) | (782) |
| Loss on marketable security | | | (324) | | | |
| Other expenses | | | (7) | (35) | (6) | |
| Income (loss) before income taxes | 3,663 | 1,539 | 700 | (305) | (11,438) | (1,702) |
| Provision for income taxes | (839) | (534) | (130) | | | |
| Net income (loss) | $ 2,824 | $ 1,005 | $ 570 | $ (305) | $ (11,438) | $ (1,702) |
| Net income (loss) per share, basic | $ 0.11 | $ 0.04 | $ 0.02 | $ (0.01) | $ (0.46) | $ (0.07) |
| Net income (loss) per share, diluted | $ 0.10 | $ 0.04 | $ 0.02 | $ (0.01) | $ (0.46) | $ (0.07) |
| Weighted-average common shares, basic | 24,926,150 | 24,926,150 | 24,926,150 | 25,022,594 | 25,126,027 | 25,000,000 |
| Weighted-average common shares, diluted | 28,776,045 | 27,697,832 | 28,356,133 | 25,022,594 | 25,126,027 | 25,000,000 |

Table of Contents

| | June 30, | | December 31, | | | |
|---|---|---|---|---|---|---|
| | 2008 | 2007 | 2007 | 2006 | 2005 | 2004 |
| | (In thousands) | | | | | |
| **Balance Sheet Data:** | | | | | | |
| Cash and cash equivalents | $ 19 | $ 548 | $ 241 | $ 116 | $ 959 | $ 4,008 |
| Working capital | (3,504) | (5,941) | (5,131) | (9,230) | (11,740) | 652 |
| Total assets | 21,321 | 13,244 | 15,909 | 10,582 | 16,147 | 21,019 |
| Long-term debt, net of current portion | 11,911 | 10,382 | 12,371 | 10,382 | 13,031 | 13,074 |
| Accumulated deficit | (10,274) | (12,663) | (13,098) | (13,668) | (13,140) | (1,702) |
| Total stockholders deficit | (9,302) | (12,198) | (12,295) | (13,844) | (12,903) | (1,654) |

Table of Contents

**Selected Unaudited Pro Forma Condensed Combined Financial Data of Critical Therapeutics and Cornerstone**

The following unaudited pro forma condensed combined financial statements give effect to the merger of a wholly owned subsidiary of Critical Therapeutics and Cornerstone in a transaction to be accounted for as a purchase with Cornerstone treated as the acquirer even though Critical Therapeutics will be the issuer of common stock and surviving legal entity in the transaction (based in part on the fact that upon completion of the merger Critical Therapeutics stockholders will retain approximately 30% and the former Cornerstone stockholders will own approximately 70% of the outstanding shares of Critical Therapeutics, assuming the exchange or conversion prior to the merger of the outstanding principal amount of the Carolina Note into shares of Cornerstone s common stock and after giving effect to shares issuable pursuant to Cornerstone s outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics outstanding options and warrants). The unaudited pro forma condensed statements of operations are based on the individual historical consolidated statements of operations of Critical Therapeutics and Cornerstone and combine the results of operations of Critical Therapeutics and Cornerstone for the year ended December 31, 2007 and the six months ended June 30, 2008, giving effect to the combination as if it occurred on January 1, 2007, reflecting only pro forma adjustments expected to have a continuing impact on the combined results. The unaudited pro forma condensed balance sheet combines the historical consolidated balance sheets of Critical Therapeutics and Cornerstone as of June 30, 2008, giving effect to the combination as if it occurred on June 30, 2008, reflecting only pro forma adjustments expected to have a continuing impact on the combined results. The unaudited pro forma condensed combined financial information does not give effect to the proposed reverse stock split as it is currently unknown which ratio, if any, will be used.

These unaudited pro forma condensed combined financial statements are for informational purposes only. They do not purport to indicate the results that would have actually been obtained had the merger been completed on the assumed date or for the periods presented, or that may be realized in the future. To produce the unaudited pro forma financial information, Cornerstone, as the acquiring party, preliminarily allocated the purchase price using its best estimates of fair value. These estimates are based on the most recently available information. To the extent there are significant changes to Critical Therapeutics business, the assumptions and estimates herein could change significantly. Furthermore, the parties may have reorganization and restructuring expenses as well as potential operating efficiencies as a result of combining the companies. The pro forma financial information does not reflect these potential expenses and efficiencies. Upon completion of the merger, final valuations will be performed. The unaudited pro forma condensed combined financial statements should be read in conjunction with Critical Therapeutics Management s Discussion and Analysis of Financial Condition and Results of Operations and Cornerstone s Management s Discussion and Analysis of Financial Condition and Results of Operations and the historical consolidated financial statements, including related notes of Critical Therapeutics and Cornerstone, respectively, covering these periods, included in this proxy statement/prospectus. Please see the section entitled Where You Can Find More Information on page 352 of this proxy statement/prospectus for more information.

Table of Contents

| | Six Months Ended June 30, 2008 | Year Ended December 31, 2007 |
|---|---|---|
| | (In thousands) | |
| **Unaudited Pro Forma Condensed Combined Statements of Operations Data:** | | |
| Net revenues | $ 30,739 | $ 40,940 |
| Operating expenses: | | |
| Cost of products sold | 10,959 | 10,942 |
| Research and development | 7,532 | 22,603 |
| Sales, general and administrative | 25,713 | 45,718 |
| Restructuring charges | 1,204 | |
| Total costs and expenses | 45,408 | 79,263 |
| Other (expense) income | (518) | 70 |
| Loss before income taxes | (15,187) | (38,253) |
| Provision for income taxes | 839 | 130 |
| Net loss | $ (16,026) | $ (38,383) |

| | As of June 30, 2008 |
|---|---|
| | (In thousands) |
| **Unaudited Pro Forma Condensed Combined Balance Sheet Data:** | |
| Cash and cash equivalents | $ 9,020 |
| Working capital | 6,528 |
| Total assets | 54,681 |
| Total liabilities | 32,652 |
| Total stockholders equity | 22,029 |

Table of Contents

**Comparative Historical and Unaudited Pro Forma Per Share Data**

*The following information does not give effect to the reverse stock split of Critical Therapeutics common stock described in Proposal 2.*

The information below reflects the historical net loss and book value per share of Cornerstone s common stock and the historical net loss and book value per share of Critical Therapeutics common stock in comparison with the unaudited pro forma net loss and book value per share after giving effect to the proposed merger of Critical Therapeutics with Cornerstone on a purchase basis.

You should read the tables below in conjunction with the audited and unaudited financial statements of Critical Therapeutics beginning on page F-3 of this proxy statement/prospectus and the audited and unaudited financial statements of Cornerstone commencing at page F-54 of this proxy statement/prospectus and the related notes and the unaudited pro forma condensed combined financial information and notes related to such financial statements included elsewhere in this proxy statement/prospectus. The pro forma financial information is presented for illustrative purposes only and is not necessarily indicative of the results of operations that would have resulted if the merger had been completed as of the assumed dates or of the results that will be achieved in the future.

The selected unaudited pro forma condensed combined financial data as of and for the six months ended June 30, 2008 and for the year ended December 31, 2007 are derived from the unaudited pro forma condensed combined financial information beginning on page 328 of this proxy statement/prospectus and should be read in conjunction with that information. Please see the section entitled Unaudited Pro Forma Condensed Combined Financial Information beginning on page 327 of this proxy statement/prospectus.

**CRITICAL THERAPEUTICS**

| | Year Ended December 31, 2007 | Six Months Ended June 30, 2008 |
|---|---|---|
| **Historical Per Common Share Data:** | | |
| Net loss per common share, basic and diluted | $ (0.87) | $ (0.41) |
| Book value per common share as of the end of the period | $ 0.40 | $ 0.03 |

**CORNERSTONE**

| | Year Ended December 31, 2007 | Six Months Ended June 30, 2008 |
|---|---|---|
| **Historical Per Common Share Data:** | | |
| Net income per common share, basic | $ 0.02 | $ 0.11 |
| Net income per common share, diluted | $ 0.02 | $ 0.10 |
| Book value per common share as of the end of the period | $ (0.49) | $ (0.37) |

Table of Contents

**CORNERSTONE AND CRITICAL THERAPEUTICS**

| | Year Ended December 31, 2007 | Six Months Ended June 30, 2008 |
|---|---|---|
| **Combined Unaudited Pro Forma Per Common Share Data:** | | |
| Net loss per combined common share from continuing operations, basic and diluted | $ (0.34) | $ (0.13) |
| Book value per combined common share | $ 0.21 | $ 0.18 |
| **Equivalent Pro Forma Per Common Share Data:** | | |
| Net loss per combined common share from continuing operations, basic and diluted | $ (0.96) | $ (0.33) |
| Book value per combined common share | $ 0.60 | $ 0.46 |

Table of Contents

## MARKET PRICE AND DIVIDEND INFORMATION

Critical Therapeutics common stock is listed on The NASDAQ Capital Market under the symbol CRTX. From July 2006 to June 2008, Critical Therapeutics common stock traded on the NASDAQ Global Market. Prior to July 2006, Critical Therapeutics common stock traded on The NASDAQ National Market. The following table sets forth, for the periods indicated, the high and low per share sales prices for Critical Therapeutics common stock as reported on NASDAQ. Cornerstone is a private company and its common stock is not publicly traded.

### Critical Therapeutics Common Stock

| | High | Low |
|---|---|---|
| **Year Ended December 31, 2006** | | |
| First Quarter | $ 7.41 | $ 4.72 |
| Second Quarter | 6.25 | 3.28 |
| Third Quarter | 4.50 | 2.08 |
| Fourth Quarter | 3.28 | 1.45 |
| **Year Ended December 31, 2007** | | |
| First Quarter | $ 2.72 | $ 1.44 |
| Second Quarter | 4.10 | 1.50 |
| Third Quarter | 2.54 | 1.66 |
| Fourth Quarter | 2.70 | 1.20 |
| **Year Ended December 31, 2008** | | |
| First Quarter | $ 1.45 | $ 0.67 |
| Second Quarter | 0.72 | 0.26 |
| Third Quarter (through September 26, 2008) | 0.42 | 0.12 |

On April 30, 2008, the last day prior to the public announcement of the proposed merger, the closing price per share of Critical Therapeutics common stock as reported on The NASDAQ Global Market was $0.62, for an aggregate market value of Critical Therapeutics of approximately $26,957,103. Accordingly, if the merger had been consummated on that day, the value attributable to the shares of Critical Therapeutics common stock issued to holders of Cornerstone s common stock and issuable to holders of Cornerstone s outstanding options and warrants in connection with the merger would have been approximately $62.9 million, based on approximately 101.5 million shares of Critical Therapeutics common stock issued or issuable to Cornerstone s stockholders in the merger, multiplied by $0.62.

On , 2008, the last practicable date before the printing of this proxy statement/prospectus, the closing price per share of Critical Therapeutics common stock as reported on The NASDAQ Capital Market was $ , for an aggregate market value of Critical Therapeutics of approximately $ . Accordingly, if the merger had been consummated on that day, the value attributable to the shares of Critical Therapeutics common stock issued to holders of Cornerstone s common stock and issuable to holders of Cornerstone s outstanding options and warrants in connection with the merger would have been approximately $ , based on approximately 101.5 million shares of Critical Therapeutics common stock issued or issuable to Cornerstone s stockholders in the merger multiplied by $ .

Because the market price of Critical Therapeutics common stock is subject to fluctuation, the market value of the shares of Critical Therapeutics common stock that holders of Cornerstone s common stock and

**Table of Contents**

Cornerstone s outstanding stock options and warrants will be entitled to receive in the merger may increase or decrease.

Following the consummation of the merger, and subject to successful application for initial listing with The NASDAQ Capital Market, Critical Therapeutics common stock will continue to be listed on The NASDAQ Capital Market. Although Critical Therapeutics common stock will continue with the trading symbol CRTX , it will trade under the combined company s new name, Cornerstone Therapeutics Inc. There has never been, nor is there expected to be in the future, a public market for Cornerstone s common stock.

As of , 2008 Critical Therapeutics had approximately stockholders of record.

Critical Therapeutics has never declared or paid cash dividends on its capital stock. Critical Therapeutics currently intends to retain earnings, if any, to finance the growth and development of its business, and does not expect to pay any cash dividends to its stockholders in the foreseeable future. Payment of future dividends, if any, will be at the discretion of Critical Therapeutics board of directors.

Table of Contents

## RISK FACTORS

*In addition to the other information contained in this proxy statement/prospectus, you should carefully consider the risks and uncertainties described below.*

### Risks Related to the Merger

***Some of Critical Therapeutics and Cornerstone s officers and directors have interests that may be different from yours and influence them to support or approve the merger.***

Officers and directors of Critical Therapeutics and Cornerstone participate in arrangements that provide them with interests in the merger that are different from yours, including, among others, their continued service as an officer or director of the combined company, retention and severance benefits, the acceleration of restricted stock and stock option vesting and continued indemnification.

For example, pursuant to the terms of employment agreements with Critical Therapeutics executive officers and a change of control cash bonus program established by Critical Therapeutics, upon the consummation of the merger, the executive officers of Critical Therapeutics are entitled to receive aggregate cash payments of approximately $305,000 and accelerated vesting of restricted stock with an aggregate value of approximately $16,978, assuming that the merger had been consummated on September 15, 2008. Assuming each executive officer of Critical Therapeutics is terminated other than for cause or terminates his employment for good reason, in each case as those terms are defined in his employment agreement, within specified periods before or after the consummation of the merger, then the executive officers of Critical Therapeutics would be entitled to receive aggregate cash payments of approximately $1,814,318 accelerated vesting of restricted stock with an aggregate value of approximately $33,956 and additional aggregate payments of approximately $88,150 for COBRA premiums for continued health and dental coverage, premiums for life insurance and disability insurance and outplacement services, assuming that the merger had been consummated on September 15, 2008. Although the executive officers and directors of Critical Therapeutics are entitled to accelerated vesting of unvested stock options in connection with the merger, all stock options subject to accelerated vesting have an exercise price that is greater than $0.22 per share, the closing market price of Critical Therapeutics common stock on September 15, 2008. Unvested stock options held by executive officers and directors of Critical Therapeutics that are subject to accelerated vesting have exercise prices ranging from $1.05 to $8.58 per share and a weighted average exercise price of $3.32 per share. Following the effective time of the merger, the executive management team of the combined company is expected to be composed primarily of current Cornerstone executives. It is not expected that any of the current executive officers or directors of Critical Therapeutics will continue his or her service with the combined company following the merger, other than Scott B. Townsend, Critical Therapeutics General Counsel, Senior Vice President of Legal Affairs and Secretary.

In anticipation of Mr. Townsend s service to the combined company following the merger, on September 16, 2008, Critical Therapeutics entered into an amendment to the amended and restated employment agreement between Critical Therapeutics and Mr. Townsend. This amendment will be effective from the effective time of the merger to December 31, 2010 and will only become effective if the merger is consummated. Under the terms of this amendment, Mr. Townsend will serve as the General Counsel, Executive Vice President of Legal Affairs and Secretary of the combined company. The amendment provides for an increase in Mr. Townsend s annual target cash bonus as a percentage of base salary from 30% to 35% and an actual annual cash bonus for Mr. Townsend for 2008 of not less than 35% of his base salary if he remains an employee in good standing through December 31, 2008. Mr. Townsend will continue to receive an annual base salary of $275,000. In connection with such amendment, Critical Therapeutics also entered into a restricted stock agreement with Mr. Townsend that provides for a restricted stock grant to

Mr. Townsend on the first business day after the consummation of the merger of a number of shares of common stock representing one percent of the combined company s outstanding equity, on a fully diluted basis but excluding an aggregate of 7,208,707 shares of Critical Therapeutics common stock underlying warrants issued in connection with a June 2005 private placement and an October 2006 registered offering, after giving effect to the reverse stock split and the merger, subject to the terms of such restricted stock agreement. The restricted stock agreement will only become effective if the merger is consummated. It is expected that approximately 1,489,789 shares

Table of Contents

will be issued to Mr. Townsend pursuant to the restricted stock agreement, subject to adjustment as a result of the reverse stock split. The amendment to Mr. Townsend s amended and restated employment agreement also provides for additional potential future benefits to Mr. Townsend in connection with a termination of his employment by the combined company other than for cause or by Mr. Townsend for good reason.

Cornerstone s executive officers are expected to continue as executive officers of the combined company with initial annual base salaries following the merger that are identical to their respective annual base salaries with Cornerstone immediately prior to the merger. These individuals, their expected positions and annual base salaries with the combined company are as follows:

Craig A. Collard, President and Chief Executive Officer, annual base salary of $379,600;

Chenyqua Baldwin, Vice President, Finance, Chief Accounting Officer and Controller, annual base salary of $223,600;

Brian Dickson, M.D., Chief Medical Officer, annual base salary of $270,400;

George Esgro, Vice President, Sales and Marketing, annual base salary of $220,000;

Steven M. Lutz, Executive Vice President, Manufacturing and Trade, annual base salary of $250,000; and

David Price, Executive Vice President, Finance, and Chief Financial Officer, annual base salary of $285,000.

As of May 2, 2008, the date that holders of a majority of the shares of Cornerstone s outstanding common stock acting by written consent without a meeting in accordance with Section 228 of the Delaware General Corporation Law and Cornerstone s bylaws approved the merger agreement and the transactions contemplated thereby, Mr. Collard controlled, directly or indirectly, 54% of the outstanding shares of Cornerstone s common stock, and Cornerstone s executive officers and directors, and their affiliates, in the aggregate controlled, directly or indirectly, 68.3% of the outstanding shares of Cornerstone s common stock.

Assuming that the merger had been consummated on September 15, 2008, Cornerstone s executive officers and directors, and their affiliates, would beneficially own, in the aggregate, 67,523,206 shares, or approximately 51%, of the outstanding common stock of the combined company, including any shares of the common stock of the combined company issuable in the merger in exchange for shares of Cornerstone s outstanding common stock to be issued to Carolina Pharmaceuticals upon the exchange or conversion of principal amounts under the Carolina Note into shares of Cornerstone s common stock prior to the effective time of the merger pursuant to the noteholder agreement between Carolina Pharmaceuticals and Critical Therapeutics. Additionally, Cornerstone s executive officers and directors would hold options to acquire an aggregate of 6,409,119 shares of the common stock of the combined company that are not considered beneficially owned because such options are not exercisable within sixty days of September 15, 2008.

Carolina Pharmaceuticals, which is the holder of the Carolina Note, has entered into an agreement with Critical Therapeutics that provides, among other things, for the exchange or conversion of the outstanding principal amount of the Carolina Note into shares of Cornerstone s common stock outstanding immediately prior to the effective time of the merger. Mr. Collard is the Chief Executive Officer and Chairman of the Board of Carolina Pharmaceuticals.

These interests, among others, may influence the officers and directors of Critical Therapeutics and Cornerstone to support or approve the merger. For a more detailed discussion, see The Merger Interests of Critical Therapeutics Directors and Executive Officers in the Merger and The Merger Interests of Cornerstone s Directors and Executive Officers in the Merger beginning on pages 119 and 125, respectively, of this proxy statement/prospectus.

***The merger may be completed even though material adverse changes may result from the announcement of the merger, industry-wide changes and other causes.***

In general, either party can refuse to complete the merger if there is a material adverse change affecting the other party between May 1, 2008, the date of the merger agreement, and the closing. However, some types of

Table of Contents

changes do not permit either party to refuse to complete the merger, even if such changes would have a material adverse effect on Critical Therapeutics or Cornerstone, to the extent they resulted from the following and do not have a materially disproportionate effect on Critical Therapeutics or Cornerstone, as the case may be:

- changes in prevailing economic or market conditions in the United States or any other jurisdiction in which a party has substantial business operations;
- changes or events affecting the industries in which the parties operate generally;
- changes in generally accepted accounting principles or requirements applicable to a party;
- changes in laws, rules or regulations of general applicability or interpretations thereof;
- changes caused by the execution, delivery and performance of the merger agreement and the transactions contemplated thereby;
- changes caused by any outbreak of major hostilities in which the United States is involved or any act of terrorism within the United States or directed against facilities or citizens of the United States; or
- with respect to Critical Therapeutics, specified ordinary course operational exceptions as set forth in Critical Therapeutics disclosure schedules.

In addition, if a material adverse change occurs between May 1, 2008 and the closing that affects one party, and assuming that all other closing conditions have been satisfied, the other party may, to the extent consistent with such party s obligations under Delaware and federal disclosure and securities laws, elect to complete the merger without seeking further stockholder approval, notwithstanding the material adverse change.

If adverse changes occur but Critical Therapeutics and Cornerstone must still complete the merger, the combined company s stock price may suffer.

***The market price of Critical Therapeutics common stock has fallen significantly since the public announcement of the proposed merger. If the merger is completed and the perceived benefits of the merger are not realized, the market price of the combined company s common stock may decline further.***

On April 30, 2008, the last day prior to the public announcement of the proposed merger, the closing price per share of Critical Therapeutics common stock as reported on The NASDAQ Global Market was $0.62. On , 2008, the last practicable date before the printing of this proxy statement/prospectus, the closing price per share of Critical Therapeutics common stock as reported on The NASDAQ Capital Market was $ , which represents a % decrease from the closing price on April 30, 2008. If the merger is completed, the market price of the combined company s common stock may decline further for a number of reasons, including if:

- the combined company does not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts;
- the effect of the merger on the combined company s business and prospects is not consistent with the expectations of financial or industry analysts; or
- investors react negatively to the effect on the combined company s business and prospects from the merger.

***Critical Therapeutics and Cornerstone s stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger.***

It is anticipated that, immediately following the completion of the merger, Critical Therapeutics stockholders, who prior to the closing of the merger own 100% of Critical Therapeutics common stock, will own approximately 30% of the common stock of the combined company and Cornerstone s security holders, who prior to the closing of the merger own 100% of the fully diluted common stock of Cornerstone, will own approximately 70% of the common stock of the combined company, assuming the exchange or conversion prior to the merger of the outstanding principal amount of the Carolina Note into shares of Cornerstone s

Table of Contents

common stock and after giving effect to shares issuable pursuant to Cornerstone s outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics outstanding options and warrants. Accordingly, if the combined company is unable to realize the strategic and financial benefits currently anticipated from the merger, Critical Therapeutics and Cornerstone s stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. For example, had the merger been consummated as of June 30, 2008 and assuming the net income of the combined company was comprised solely of the net income attributable to Cornerstone, the dilution of the ownership interest of Cornerstone s stockholders would have resulted in Cornerstone s earnings per share decreasing from $0.10 to $0.07 for the six months ended June 30, 2008.

***During the pendency of the merger, Critical Therapeutics and Cornerstone may not be able to enter into a business combination with another party because of restrictions in the merger agreement.***

Covenants in the merger agreement impede the ability of Critical Therapeutics or Cornerstone to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the merger. While the merger agreement is in effect and subject to limited exceptions, each party is prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to the entering into certain extraordinary transactions with any third party, such as a sale of assets, an acquisition of Critical Therapeutics common stock, a tender offer for Critical Therapeutics common stock, a merger or other business combination outside the ordinary course of business. Any such transactions could be favorable to such party s stockholders.

***Negative perceptions regarding the pending merger may harm either Critical Therapeutics or Cornerstone s business and employee relationships.***

During the pendency of the merger, uncertainty or negative perceptions regarding the merger or the combined company s business and prospects could harm relationships that either Critical Therapeutics or Cornerstone has established as an independent, standalone company. For example:

- Suppliers, distributors and other business partners may seek to change or terminate their relationships with either Critical Therapeutics or Cornerstone as a result of the proposed merger.

- As a result of the proposed merger, current and prospective employees could experience uncertainty about their future roles within the combined company. This uncertainty may adversely affect the ability of either Critical Therapeutics or Cornerstone to retain its key employees, who may seek other employment opportunities.

In addition, during the pendency of the merger, the management team of either Critical Therapeutics or Cornerstone may be distracted from day to day operations as a result of the proposed merger.

***Because the lack of a public market for the Cornerstone shares makes it difficult to evaluate the fairness of the merger, Cornerstone stockholders may receive consideration in the merger that is greater than or less than the fair market value of the Cornerstone shares.***

The outstanding capital stock of Cornerstone is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Cornerstone. Since the percentage of Critical Therapeutics equity to be issued to Cornerstone s stockholders was determined based on negotiations between the parties, it is possible that the value of the Critical Therapeutics common stock to be issued in connection with the merger will be greater than the fair market value of Cornerstone. Alternatively, it is possible that the value of the shares of Critical Therapeutics common stock to be issued in connection with the merger will be less than the fair market value of Cornerstone.

Table of Contents

***If any of the events described in Risks Related to Cornerstone occur, those events could cause the potential benefits of the merger not to be realized.***

Following the effective time of the merger, current Cornerstone officers and directors will direct the business and operations of the combined company. Additionally, Cornerstone s business is expected to constitute most, if not all, of the business of the combined company following the merger. As a result, the risks described below in the section entitled Risks Related to Cornerstone beginning on page 59 are among the most significant risks to the combined company if the merger is completed. To the extent any of the events in the risks described below in the section entitled Risks Related to Cornerstone beginning on page 59 occur, those events could cause the potential benefits of the merger not to be realized and the market price of the combined company s common stock to decline.

## Risks Related to Critical Therapeutics

### Risks Relating to Critical Therapeutics Business

***Critical Therapeutics business depends heavily on the commercial success of ZYFLO CR.***

ZYFLO CR and ZYFLO are currently Critical Therapeutics only commercially marketed products. Critical Therapeutics commercially launched ZYFLO CR on September 27, 2007. In February 2008, Critical Therapeutics discontinued the production and supply of ZYFLO, which Critical Therapeutics had commercially launched in October 2005, but Critical Therapeutics resumed the supply of ZYFLO in September 2008 to help manage the potential impact to patients of supply chain issues for ZYFLO CR. In the six months ended June 30, 2008, Critical Therapeutics experienced supply chain issues in manufacturing ZYFLO CR and recorded an inventory reserve for an aggregate of 12 batches of ZYFLO CR that could not be released into Critical Therapeutics supply chain. If Critical Therapeutics is unable to manufacture or release ZYFLO CR on a timely and consistent basis, some physicians may prescribe ZYFLO to ensure that their patients with asthma continue to have access to zileuton as a treatment option. ZYFLO, which is dosed four times per day, contains the same zileuton active pharmaceutical ingredient, or API, as ZYFLO CR, which is dosed two tablets twice daily. When prescribed as indicated in their respective labels, both ZYFLO CR and ZYFLO provide a patient with 2,400 mg of zileuton per day. Both ZYFLO CR and ZYFLO are approved by the FDA for the same indication.

ZYFLO has not achieved broad market acceptance. If Critical Therapeutics is able to successfully commercialize ZYFLO CR, Critical Therapeutics expects it will account for a significant portion of Critical Therapeutics revenues for the foreseeable future. However, Critical Therapeutics cannot assure you that ZYFLO CR will not suffer the same lack of broad market acceptance that has affected ZYFLO.

Critical Therapeutics product candidates are in early clinical and preclinical stages of development and are a number of years away from commercialization. Research and development of product candidates is a lengthy and expensive process. Critical Therapeutics early-stage product candidates in particular will require substantial funding for Critical Therapeutics to complete preclinical testing and clinical trials, initiate manufacturing and, if approved for sale, initiate commercialization. If ZYFLO CR is not commercially successful, Critical Therapeutics may be forced to find additional sources of funding earlier than Critical Therapeutics anticipated. If Critical Therapeutics is not successful in obtaining additional funding on acceptable terms, Critical Therapeutics may be forced to significantly delay, limit or eliminate one or more of Critical Therapeutics development or commercialization programs.

***If ZYFLO CR does not achieve market acceptance, Critical Therapeutics may not be able to generate significant revenues unless Critical Therapeutics is able to successfully develop and commercialize other product candidates.***

The commercial success of ZYFLO CR will depend upon its acceptance by the medical community, third-party payors and patients. Physicians will prescribe ZYFLO CR only if they determine, based on experience, clinical data, side effect profiles or other factors, that this product either alone or in combination with other

products is appropriate for managing asthma. Critical Therapeutics believes that the primary advantage of ZYFLO CR over ZYFLO is ZYFLO CR s more convenient dosing schedule, but this advantage may not result in broad market acceptance of ZYFLO CR, and Critical Therapeutics may experience the same lack of market acceptance with ZYFLO CR that Critical Therapeutics has experienced with ZYFLO.

Despite being approved by the FDA since 1996, ZYFLO did not achieve broad market acceptance. During the period between Critical Therapeutics commercial launch of ZYFLO in October 2005 through May 2008, prescription data for ZYFLO indicates that approximately 5,900 physicians prescribed the product. Critical Therapeutics recorded revenue from the sale of ZYFLO of $8.7 million for the year ended December 31, 2007 and $748,000 for the six months ended June 30, 2008. Critical Therapeutics recorded revenue from the sale of ZYFLO CR of $2.3 million for the year ended December 31, 2007 and $6.5 million for the six months ended June 30, 2008. Critical Therapeutics experienced difficulty expanding the prescriber and patient bases for ZYFLO, in part, Critical Therapeutics believes, because some physicians view ZYFLO as less effective than other products on the market or view its clinical data as outdated and because it requires dosing of one tablet four times per day, which some physicians and patients may find inconvenient or difficult to comply with compared to other available asthma therapies that require dosing only once or twice daily. In addition, if physicians do not prescribe ZYFLO CR for the recommended dosing regimen of two tablets twice daily, or if patients do not comply with the dosing schedule and take less than the prescribed number of tablets, Critical Therapeutics sales of ZYFLO CR will be limited and Critical Therapeutics revenues will be adversely affected.

The position of ZYFLO CR in managed care formularies, which are lists of approved products developed by managed care organizations, or MCOs, may make it more difficult to expand the current market share for this product. In most instances, ZYFLO CR and ZYFLO have been placed in formulary positions that require a higher co-payment for patients. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for ZYFLO CR.

If any existing negative perceptions about ZYFLO persist, Critical Therapeutics will have difficulty achieving market acceptance for ZYFLO CR. If Critical Therapeutics is unable to achieve market acceptance of ZYFLO CR, Critical Therapeutics will not generate significant revenues unless Critical Therapeutics is able to successfully develop and commercialize other product candidates.

***Concerns regarding the safety profile of ZYFLO CR may limit market acceptance of ZYFLO CR, and, if significant adverse events related to ZYFLO CR occur, Critical Therapeutics may be exposed to product liability claims.***

Market perceptions about the safety of ZYFLO also may limit the market acceptance of ZYFLO CR. In the clinical trials that were reviewed by the FDA prior to its approval of ZYFLO, 3.2% of the approximately 5,000 patients who received ZYFLO experienced increased levels of a liver enzyme called alanine transaminase, or ALT, of over three times the levels normally seen in the bloodstream. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin. In clinical trials for ZYFLO CR, 1.94% of the patients taking ZYFLO CR in a three-month efficacy trial and 2.6% of the patients taking ZYFLO CR in a six-month safety trial experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream. Because ZYFLO CR can elevate liver enzyme levels, periodic liver function tests are recommended for patients taking ZYFLO CR, based upon its product label, which was approved by the FDA in May 2007.

Some physicians and patients may perceive liver function tests as inconvenient or indicative of safety issues, which could make them reluctant to prescribe or accept ZYFLO CR and any other zileuton product candidates that Critical Therapeutics successfully develops and commercializes. As a result, many physicians may have negative perceptions about the safety of ZYFLO CR and other zileuton product candidates, which could limit their commercial acceptance.

The absence of ZYFLO from the market prior to Critical Therapeutics commercial launch in October 2005 may have exacerbated any negative perceptions about ZYFLO if

Table of Contents

physicians believe the absence of ZYFLO from the market was related to safety or efficacy issues. These negative perceptions could carry over to ZYFLO CR.

In March 2008, the FDA issued an early communication regarding an ongoing safety review of the leukotriene montelukast relating to suicide and other behavior related adverse events. In that communication, the FDA stated that it was also reviewing the safety of other leukotriene medications. On May 27, 2008, Critical Therapeutics received a request from the FDA that Critical Therapeutics gather and provide to the FDA data from its clinical trial database to evaluate behavior-related adverse events for ZYFLO and ZYFLO CR. Depending on the results of such analyses and the FDA s review, the FDA could request that Critical Therapeutics revise the labeling of ZYFLO and ZYFLO CR to include statements regarding the potential for suicidal thoughts or other behavior-related changes associated with the use of zileuton. If the FDA requests that Critical Therapeutics add these statements or similar statements to its package inserts, sales of these products could suffer.

If the use of ZYFLO CR or ZYFLO harms people, Critical Therapeutics may be subject to costly and damaging product liability claims. Critical Therapeutics currently has products liability insurance coverage with a $20.0 million annual aggregate limit and a $20.0 million individual claim limit, which is subject to a per claim deductible and a policy aggregate deductible. This product liability insurance covers both product liability claims for ZYFLO CR and ZYFLO and clinical trial liability claims for Critical Therapeutics product candidates. The annual cost of this products liability insurance was approximately $400,000 for the policy year starting October 29, 2007. This insurance policy may not provide adequate coverage against potential liabilities. Furthermore, product liability and clinical trial insurance is becoming increasingly expensive. As a result, Critical Therapeutics may be unable to maintain current amounts of insurance coverage, obtain additional insurance or obtain sufficient insurance at a reasonable cost to protect against losses that Critical Therapeutics has not anticipated in its business plans. Any product liability claim against Critical Therapeutics, even if Critical Therapeutics successfully defends against it, could cause Critical Therapeutics to incur significant legal expenses, divert Critical Therapeutics management s attention and harm Critical Therapeutics reputation.

***If Critical Therapeutics marketing and sales infrastructure and presence are not adequate or Critical Therapeutics collaborative marketing arrangements are not successful, Critical Therapeutics ability to market and sell its products will be impaired.***

After increasing the size of Critical Therapeutics sales force in connection with the commercial launch of ZYFLO CR to approximately 42 sales representatives in October 2007, Critical Therapeutics decreased the size of its sales force to approximately 29 sales representatives as of June 30, 2008. Building Critical Therapeutics sales force involved significant time and expense. If Critical Therapeutics is not successful in its efforts to retain an adequate sales force, its ability to market and sell ZYFLO CR will be impaired.

In March 2007, Critical Therapeutics entered into a co-promotion agreement with Dey, L.P., a wholly owned subsidiary of Mylan Inc., or DEY, for the co-promotion of ZYFLO CR and ZYFLO. Critical Therapeutics cannot predict whether the co-promotion arrangement will lead to increased sales for ZYFLO CR. DEY initiated promotional detailing activities for ZYFLO CR on September 27, 2007 and for ZYFLO on April 30, 2007. Given the recent initiation of DEY s efforts, the potential success of the co-promotion arrangement is uncertain. Under the co-promotion agreement, Critical Therapeutics agreed to provide a minimum number of promotional details per month by Critical Therapeutics sales representatives to a specified group of office-based physicians and other health care professionals for ZYFLO CR. If Critical Therapeutics is not successful in its efforts to provide the required level of promotional detailing, DEY s co-promotion fee may be increased and DEY may have a right to terminate the co-promotion agreement for ZYFLO CR. For example, if Critical Therapeutics experiences greater than expected turnover of sales representatives, Critical Therapeutics may have difficulty satisfying its minimum detailing obligations. In February 2008, Mylan Inc., or Mylan, which acquired DEY in October 2007 as part of its acquisition of Merck KGaA s generic

business, of which DEY was a part, announced that it is pursuing strategic alternatives for DEY, including the potential sale of the business. Any decision by DEY or Mylan not to devote sufficient resources to the co-promotion arrangement or any future reductions in efforts under the co-promotion arrangement, including as a result of the sale or

Table of Contents

potential sale of DEY by Mylan, would limit Critical Therapeutics ability to generate significant revenues from product sales.

On June 25, 2007, as contemplated by the terms of the zileuton co-promotion agreement, Critical Therapeutics and DEY entered into a separate definitive co-promotion agreement providing for Critical Therapeutics to co-promote DEY s product PERFOROMIST™ (formoterol fumarate) Inhalation Solution, or PERFOROMIST, for the long-term, twice-daily maintenance treatment of bronchoconstriction for emphysema and chronic bronchitis, which is also known as chronic obstructive pulmonary disease, or COPD. Under the PERFOROMIST co-promotion agreement, DEY agreed to pay Critical Therapeutics a co-promotion fee based on retail sales of PERFOROMIST and Critical Therapeutics agreed to provide a minimum number of promotional details per month by Critical Therapeutics sales representatives to a specified group of office-based physicians and other health care professionals. Promoting both ZYFLO CR and PERFOROMIST may be challenging for Critical Therapeutics sales representatives and may reduce their efficiency, which could negatively impact Critical Therapeutics revenues.

The amount of any co-promotion fee that DEY pays to Critical Therapeutics under the PERFOROMIST co-promotion agreement will be limited if PERFOROMIST does not achieve market acceptance. For example, safety concerns relating to PERFOROMIST may harm potential sales. PERFOROMIST belongs to a class of medications known as long-acting beta2-adrenergic agonists, or LABAs, which may increase the risk of asthma-related death. Data from a large placebo-controlled study in the United States comparing the safety of the LABA salmeterol or placebo plus usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding also may apply to formoterol, the active ingredient in PERFOROMIST. For the year ended December 31, 2007 and the six months ended June 30, 2008, Critical Therapeutics did not receive any co-promotion fees from DEY in connection with the PERFOROMIST co-promotion agreement because the level of quarterly retail sales for PERFOROMIST did not exceed a specified level. On July 2, 2008, Critical Therapeutics provided notice to DEY that Critical Therapeutics had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

***A failure to maintain appropriate inventory levels could harm Critical Therapeutics reputation and subject Critical Therapeutics to financial losses.***

Critical Therapeutics is subject to minimum purchase obligations under its supply agreements with its third-party manufacturers, which require Critical Therapeutics to buy inventory of the zileuton API and tablet cores for ZYFLO CR. Critical Therapeutics has committed to purchase a minimum amount of zileuton API from Shasun of $2.0 million in 2008 and $2.0 million in 2009, although Critical Therapeutics has the right to reduce by $1.3 million the amount of zileuton API it must purchase in 2009 by providing written notice to Shasun no later than December 31, 2008. The API purchased from Shasun currently has a shelf-life of 36 months. In addition, Critical Therapeutics has committed to purchase a minimum of 20 million ZYFLO CR tablet cores from Jagotec in each of the four 12-month periods starting May 30, 2008. If ZYFLO CR does not achieve the level of demand Critical Therapeutics anticipates, Critical Therapeutics may not be able to use the inventory it is required to purchase. As of June 30, 2008, Critical Therapeutics had $7.8 million in inventory, consisting primarily of tablet cores and API. Based on Critical Therapeutics current expectations regarding demand for ZYFLO CR, Critical Therapeutics expects that its inventory levels could increase substantially in the future as a result of its minimum purchase obligations under its supply agreements with third-party manufacturers and orders it has submitted to date. Significant differences between Critical Therapeutics current estimates and judgments and future estimated demand for its products and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. If Critical Therapeutics is required to recognize charges for excess inventories, it could have a material adverse effect on Critical Therapeutics financial condition and results of operations in the period in which Critical Therapeutics recognizes charges for excess inventory.

In the six months ended June 30, 2008, Critical Therapeutics recorded an inventory reserve for an aggregate of 12 batches of ZYFLO CR that could not be released into Critical Therapeutics commercial supply chain, consisting of five batches that did not meet Critical Therapeutics product release specifications and seven additional batches that were on quality assurance hold and that could not complete manufacturing within the

Table of Contents

manufacturing timelines specified pursuant to the new drug application, or NDA, for ZYFLO CR. Critical Therapeutics cannot assure you that it will not have similar manufacturing issues in producing ZYFLO CR in the future. If Critical Therapeutics is unable to manufacture or release ZYFLO CR on a timely and consistent basis, if Critical Therapeutics fails to maintain an adequate inventory of zileuton API or ZYFLO CR core tablets, if Critical Therapeutics inventory were to be destroyed or damaged, or if Critical Therapeutics inventory were to reach its expiration date, patients might not have access to ZYFLO CR, Critical Therapeutics reputation and its brand could be harmed and physicians may be less likely to prescribe ZYFLO CR in the future. Conversely, if Critical Therapeutics is unable to sell Critical Therapeutics inventory in a timely manner, Critical Therapeutics could experience cash flow difficulties and additional financial losses.

***Critical Therapeutics faces substantial competition. If Critical Therapeutics is unable to compete effectively, ZYFLO CR, ZYFLO and Critical Therapeutics product candidates may be rendered noncompetitive or obsolete.***

The development and commercialization of new drugs is highly competitive. Critical Therapeutics will face competition with respect to the development of product candidates and for ZYFLO CR, ZYFLO and any other products that Critical Therapeutics commercializes in the future from pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies, companies selling low-cost generic substitutes, academic institutions, government agencies and research institutions.

A number of large pharmaceutical and biotechnology companies currently market and sell products to treat asthma that compete with ZYFLO CR and ZYFLO. Many established therapies currently command large market shares in the asthma market, including Merck & Co., Inc. s Singulair®, GlaxoSmithKline plc s Advair® and inhaled corticosteroid products. In addition, Critical Therapeutics may face competition from pharmaceutical companies seeking to develop new drugs for the asthma market. For example, in June 2007, AstraZeneca PLC commercially launched in the United States Symbicort®, a twice-daily asthma therapy combining budesonide, an inhaled corticosteroid, and formoterol, a long-acting beta2-agonist.

In the COPD market, zileuton, if Critical Therapeutics is able to develop it as a treatment for COPD, will face intense competition. COPD patients are currently treated primarily with a number of medications that are indicated for COPD, asthma or both COPD and asthma. The primary products used to treat COPD are anticholinergics, long-acting beta-agonists and combination long-acting beta-agonists and inhaled corticosteroids. These medications are delivered in various device formulations, including metered dose inhalers, dry powder inhalers and by nebulization. Lung reduction surgery is also an option for COPD patients.

Many therapies for COPD are already well established in the respiratory marketplace, including GlaxoSmithKline s Advair® and Serevent® and Spiriva®, a once-daily muscarinic antagonist from Boehringer Ingleheim GmbH and Pfizer. Other novel approaches are also in development.

Critical Therapeutics is also developing zileuton injection for use in the hospital emergency department for the treatment of acute asthma attacks. Critical Therapeutics may face intense competition from companies seeking to develop new drugs for use in severe acute asthma attacks. For example, Merck & Co., Inc. has conducted clinical trials of an intravenous formulation of its product Singulair®.

If Critical Therapeutics therapeutic programs directed toward the body s inflammatory response result in commercial products, such products will compete predominantly with therapies that have been approved for diseases such as rheumatoid arthritis, like Amgen, Inc. s Enbrel®, Johnson & Johnson s Remicade®, Bristol-Myers Squibb Company s Orencia®, Abbott Laboratories Humira® and Rituxan® marketed by Biogen Idec Inc. and Genentech, Inc., and diseases such as sepsis, like Eli Lilly and Company s Xigris®. Other companies are developing therapies directed towards cytokines. Critical Therapeutics does not know whether any or all of these products under development will

ever reach the market and if they do, whether they will do so before or after Critical Therapeutics products are approved.

Table of Contents

Critical Therapeutics competitors products may be safer, more effective, more convenient or more effectively marketed and sold, than any of Critical Therapeutics products. Many of Critical Therapeutics competitors have:

- significantly greater financial, technical and human resources than Critical Therapeutics has and may be better equipped to discover, develop, manufacture and commercialize products;
- more extensive experience than Critical Therapeutics has in conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;
- competing products that have already received regulatory approval or are in late-stage development; and
- collaborative arrangements in Critical Therapeutics target markets with leading companies and research institutions.

Critical Therapeutics will face competition based on the safety and effectiveness of Critical Therapeutics products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Critical Therapeutics competitors may develop or commercialize more effective, safer or more affordable products, or obtain more effective patent protection, than Critical Therapeutics is able to. Accordingly, Critical Therapeutics competitors may commercialize products more rapidly or effectively than Critical Therapeutics is able to, which would adversely affect Critical Therapeutics competitive position, the likelihood that its product candidates will achieve initial market acceptance and its ability to generate meaningful revenues from its product candidates. Even if Critical Therapeutics product candidates achieve initial market acceptance, competitive products may render its products obsolete or noncompetitive. If Critical Therapeutics product candidates are rendered obsolete, it may not be able to recover the expenses of developing and commercializing those product candidates.

***If Critical Therapeutics is unable to retain key personnel and hire additional qualified personnel, Critical Therapeutics may not be able to achieve its goals.***

Critical Therapeutics success depends in large part on its ability to attract, retain and motivate qualified management and commercial personnel. Critical Therapeutics is highly dependent on the principal members of its executive management team. The loss of the services of any one or more of the members of Critical Therapeutics executive management team would diminish the knowledge and experience that Critical Therapeutics, as an organization, possesses and might significantly delay or prevent the achievement of Critical Therapeutics research, development or commercialization objectives and could cause Critical Therapeutics to incur additional costs to recruit replacement executive personnel. Critical Therapeutics does not maintain key person life insurance on any of the members of its executive management team.

On March 2, 2008, Frank E. Thomas resigned as Critical Therapeutics President and Chief Executive Officer effective March 31, 2008 and as a member of Critical Therapeutics board of directors effective March 2, 2008. On March 4, 2008, Critical Therapeutics announced that its board of directors appointed Trevor Phillips, Ph.D. as President and Chief Executive Officer effective April 1, 2008 and elected Dr. Phillips as a member of Critical Therapeutics board of directors effective March 4, 2008. Dr. Phillips previously had served as Critical Therapeutics Chief Operating Officer and Senior Vice President of Operations. In addition to Dr. Phillips, Critical Therapeutics also depends, in particular, on the continuing services of Thomas P. Kelly, Critical Therapeutics Chief Financial Officer and Senior Vice President of Finance and Corporate Development, and other members of Critical Therapeutics executive management team. Since June 1, 2006, Critical Therapeutics has experienced significant turnover on its executive management team, with five executive officers, including Mr. Thomas, leaving Critical Therapeutics and one executive officer joining Critical Therapeutics. If Critical Therapeutics is unsuccessful in transitioning its smaller executive

management team to compensate for the loss of Mr. Thomas and these other executives, the achievement of Critical Therapeutics research, financial, development and commercialization objectives could be significantly delayed or may not occur. In addition, Critical Therapeutics focus on transitioning to its new management

Table of Contents

team could divert its management s attention from other business concerns. Furthermore, if Critical Therapeutics decides to recruit new executive personnel, Critical Therapeutics will incur additional costs.

Recruiting and retaining qualified commercial personnel, in addition to Critical Therapeutics executive management team, will also be critical to Critical Therapeutics success. Any expansion into areas and activities requiring additional expertise, such as clinical trials, governmental approvals, contract manufacturing and sales and marketing, will place additional requirements on Critical Therapeutics management, operational and financial resources. These demands may require Critical Therapeutics to hire additional personnel and will require Critical Therapeutics existing management personnel to develop additional expertise. Critical Therapeutics faces intense competition for personnel. The failure to attract and retain personnel or to develop such expertise could delay or halt the research, development, regulatory approval and commercialization of Critical Therapeutics product candidates.

Critical Therapeutics has experienced turnover in its sales and marketing team. For example, Critical Therapeutics has experienced an increase in the number of voluntary resignations of its sales and marketing personnel after it publicly announced in November 2007 that it was in the process of reviewing a range of strategic alternatives that could result in potential changes to its current business strategy and future operations. The pendency of Critical Therapeutics proposed merger with Cornerstone could have a similar effect. In June 2008, Critical Therapeutics reduced the size of its sales force by eight sales representatives and three sales managers. If Critical Therapeutics is not successful in its efforts to retain its remaining qualified sales and marketing personnel, Critical Therapeutics ability to market and sell ZYFLO CR and Critical Therapeutics ability to deliver Critical Therapeutics required level of promotional detailing under Critical Therapeutics co-promotion agreements with DEY would be impaired.

Critical Therapeutics has also experienced turnover on its board of directors. For example, Critical Therapeutics has had eight directors leave its board and three directors join its board since June 1, 2006. Critical Therapeutics currently has four directors serving on its board. If Critical Therapeutics board were to fail to satisfy the requirements of relevant rules and regulations of the SEC and NASDAQ relating to director independence or membership on board committees, this could result in the delisting of Critical Therapeutics common stock from NASDAQ or could adversely affect investors confidence in Critical Therapeutics and Critical Therapeutics ability to access the capital markets. If Critical Therapeutics is unable to attract and retain qualified directors, the achievement of Critical Therapeutics corporate objectives could be significantly delayed or may not occur.

***Critical Therapeutics identified a material weakness in its internal control over financial reporting for the second quarter and third quarter of 2007. If Critical Therapeutics fails to achieve and maintain effective internal control over financial reporting, Critical Therapeutics could face difficulties in preparing timely and accurate financial reports, which could result in a loss of investor confidence in Critical Therapeutics reported results and a decline in Critical Therapeutics stock price.***

In connection with the preparation of Critical Therapeutics financial statements for the second quarter of 2007, Critical Therapeutics identified a material weakness in its internal control over financial reporting. This material weakness related to the operation of controls over accounting for non-routine transactions, specifically the accrual of milestone obligations due under certain of Critical Therapeutics contractual arrangements in accordance with GAAP. As a result of this material weakness, a material adjustment was recorded to Critical Therapeutics draft interim financial statements after the financial close of the second quarter of 2007. While Critical Therapeutics internal disclosure controls and procedures detected the need to accrue for the milestone obligations, Critical Therapeutics did not initially reach the appropriate conclusion relative to the timing of the accrual recognition. As a result of this material weakness, Critical Therapeutics management concluded that Critical Therapeutics disclosure controls and procedures were not effective as of either June 30, 2007 or September 30, 2007. Critical Therapeutics implemented steps to remedy the material weakness, and Critical Therapeutics management provided an unqualified assessment of Critical Therapeutics internal control over financial reporting as of December 31, 2007. There were no material

changes in Critical Therapeutics internal control over financial reporting for the quarter ended June 30, 2008. Any failure or difficulties in maintaining these procedures and controls could cause Critical Therapeutics to fail to meet its periodic reporting

Table of Contents

obligations or result in its inability to prevent or detect material misstatements in its financial statements. It is possible that Critical Therapeutics management may not be able to provide an unqualified assessment of Critical Therapeutics internal control over financial reporting or disclosure controls and procedures in the future, or be able to provide quarterly certifications that Critical Therapeutics disclosure controls and procedures are effective. It is also possible that Critical Therapeutics may identify additional significant deficiencies or material weaknesses in Critical Therapeutics internal control over financial reporting in the future. Any material weakness, or any remediation thereof that is ultimately unsuccessful, could cause investors to lose confidence in the accuracy and completeness of Critical Therapeutics financial statements, which in turn could harm Critical Therapeutics business, lead to a decline in Critical Therapeutics stock price and restrict Critical Therapeutics ability to raise additional funds needed for the growth of its business.

**Risks Relating to Critical Therapeutics Dependence on Third Parties**

***Critical Therapeutics relies on third parties to manufacture and supply the zileuton API, ZYFLO CR, ZYFLO and Critical Therapeutics product candidates. Critical Therapeutics expects to continue to rely on these sole source suppliers for these purposes and would incur significant costs to independently develop manufacturing facilities.***

Critical Therapeutics has no manufacturing facilities and limited manufacturing experience. In order to continue to commercialize ZYFLO CR and ZYFLO, develop product candidates, apply for regulatory approvals and commercialize Critical Therapeutics product candidates, Critical Therapeutics needs to develop, contract for or otherwise arrange for the necessary manufacturing capabilities. Critical Therapeutics expects to continue to rely on third parties for production of the zileuton API, commercial supplies of ZYFLO CR, commercial supplies of ZYFLO and preclinical and clinical supplies of Critical Therapeutics product candidates. These third parties are currently Critical Therapeutics sole source suppliers, and Critical Therapeutics expects to continue to rely on them for these purposes for the foreseeable future.

Critical Therapeutics has contracted with Shasun Pharma Solutions Ltd., or Shasun, for commercial production of the zileuton API, subject to specified limitations, through December 31, 2010. Zileuton API is used in Critical Therapeutics FDA-approved oral zileuton products, ZYFLO CR and ZYFLO, as well as in Critical Therapeutics zileuton injection product candidate. Critical Therapeutics only source of supply for zileuton API is Shasun, which manufactures the zileuton API in the United Kingdom. The manufacturing process for the zileuton API involves an exothermic reaction that generates heat and, if not properly controlled by the safety and protection mechanisms in place at the manufacturing sites, could result in unintended combustion of the product. The manufacture of the zileuton API could be disrupted or delayed if a batch is discontinued or damaged, if the manufacturing sites are damaged, or if local health and safety regulations require a third-party manufacturer to implement additional safety procedures or cease production. In addition, there is only one qualified supplier of a chemical known as 2-ABT, which is one of the starting materials for zileuton, and if that manufacturer stops manufacturing 2-ABT, is unable to manufacture 2-ABT or is unwilling to manufacture 2-ABT on commercially reasonable terms or at all, Shasun may be unable to manufacture API for Critical Therapeutics.

Critical Therapeutics has contracted with Jagotec AG, or Jagotec, a subsidiary of SkyePharma PLC, or SkyePharma, for the manufacture of core tablets for ZYFLO CR for commercial sale. Critical Therapeutics only source of supply for the core tablets of ZYFLO CR is Jagotec, which manufactures them in France. The manufacture of the core tablets for ZYFLO CR could be disrupted or delayed if one or more batches are discontinued or damaged or if the manufacturing site were damaged or destroyed.

Critical Therapeutics has contracted with Patheon Pharmaceuticals Inc., or Patheon, to coat and package the core tablets of ZYFLO CR for commercial sale. Patheon is currently Critical Therapeutics only source of finished ZYFLO CR tablets. The manufacture of the finished ZYFLO CR tablets could be disrupted or delayed if one or more batches

are discontinued or damaged or if the manufacturing site were damaged or destroyed.

Critical Therapeutics has contracted with Patheon to manufacture ZYFLO tablets for commercial sale. Patheon is currently Critical Therapeutics only source of finished ZYFLO tablets. The manufacture of the finished

Table of Contents

ZYFLO tablets could be disrupted or delayed if one or more batches are discontinued or damaged or if the manufacturing site were damaged or destroyed.

Critical Therapeutics is dependent upon Shasun, Patheon and Jagotec as sole providers, and will be dependent on any other third parties who manufacture Critical Therapeutics product candidates, to perform their obligations in a timely manner and in accordance with applicable government regulations. If third-party manufacturers with whom Critical Therapeutics contracts fail to perform their obligations, Critical Therapeutics may be adversely affected in a number of ways, including the following:

- Critical Therapeutics may not be able to meet commercial demands for ZYFLO CR and ZYFLO;
- Critical Therapeutics may be required to cease distribution or issue recalls;
- Critical Therapeutics may not be able to initiate or continue clinical trials of its product candidates that are under development; and
- Critical Therapeutics may be delayed in submitting applications for regulatory approvals for its product candidates.

If Shasun, Patheon or Jagotec experiences any significant difficulties in their respective manufacturing processes for Critical Therapeutics products, including the zileuton API, ZYFLO CR core tablets or finished product for ZYFLO CR and ZYFLO, Critical Therapeutics could experience significant interruptions in the supply of ZYFLO CR and ZYFLO. Critical Therapeutics inability to coordinate the efforts of its third-party manufacturing partners, or the lack of capacity or the scheduling of manufacturing sufficient for Critical Therapeutics needs at Critical Therapeutics third-party manufacturing partners, could impair Critical Therapeutics ability to supply ZYFLO CR and ZYFLO at required levels. Such an interruption could cause Critical Therapeutics to incur substantial costs and impair Critical Therapeutics ability to generate revenue from ZYFLO CR and ZYFLO may be adversely affected.

The zileuton API is manufactured in the United Kingdom by Shasun, and Critical Therapeutics either stores the zileuton API at a Shasun warehouse or ships the zileuton API either directly to a contract manufacturer or to a third-party warehouse. For the manufacture of ZYFLO CR, Critical Therapeutics ships zileuton API to France for manufacturing of core tablets by Jagotec and Critical Therapeutics ships core tablets from France to the United States to be coated, packaged and labeled at Patheon. For the manufacture of ZYFLO, Critical Therapeutics ships zileuton API to the United States to be manufactured, packaged and labeled at Patheon. While in transit, Critical Therapeutics zileuton API and ZYFLO CR core tablets, each shipment of which is of significant value, could be lost or damaged. Moreover, at any time after shipment from Shasun, Critical Therapeutics zileuton API, which is stored in France at Jagotec or in the United States at Patheon or at third-party warehouse, or Critical Therapeutics ZYFLO CR core tablets, which are stored at Patheon prior to coating and packaging, and Critical Therapeutics finished ZYFLO CR and ZYFLO products, which are stored at Critical Therapeutics third-party logistics provider, Integrated Commercialization Solutions, Inc., or ICS, could be lost or suffer damage, which would render them unusable. Critical Therapeutics has attempted to take appropriate risk mitigation steps and to obtain transit insurance. However, depending on when in the process the zileuton API, ZYFLO CR core tablets or finished product is lost or damaged, Critical Therapeutics may have limited recourse for recovery against its manufacturers or insurers. As a result, Critical Therapeutics financial performance could be impacted by any such loss or damage to its zileuton API, ZYFLO CR core tablets or finished products.

Critical Therapeutics may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. If Critical Therapeutics were required to change manufacturers for the zileuton API, ZYFLO CR tablet cores, ZYFLO or ZYFLO CR or coating, Critical Therapeutics would be required to verify that the new manufacturer

maintains facilities and procedures that comply with quality standards and all applicable regulations and guidelines, including FDA requirements and approved NDA product specifications. In addition, Critical Therapeutics would be required to conduct additional clinical bioequivalence trials to demonstrate that the finished product manufactured by the new manufacturer is equivalent to the finished product manufactured by Critical Therapeutics current manufacturer. Any delays associated with the verification of a new

Table of Contents

manufacturer or conducting additional clinical bioequivalence trials could adversely affect Critical Therapeutics production schedule or increase Critical Therapeutics production costs.

Critical Therapeutics has not secured a long-term commercial supply arrangement for any of its product candidates other than the zileuton API, which is used in zileuton injection. The manufacturing process for Critical Therapeutics product candidates is an element of the FDA approval process. Critical Therapeutics will need to contract with manufacturers who can meet the FDA requirements, including current Good Manufacturing Practices, on an ongoing basis. In addition, if Critical Therapeutics receives the necessary regulatory approval for its product candidates, Critical Therapeutics also expects to rely on third parties, including Critical Therapeutics collaborators, to produce materials required for commercial production. Critical Therapeutics may experience difficulty in obtaining adequate manufacturing capacity or timing for its needs. If Critical Therapeutics is unable to obtain or maintain contract manufacturing of these product candidates, or to do so on commercially reasonable terms, Critical Therapeutics may not be able to develop and commercialize its product candidates successfully.

***Difficulties relating to the supply chain for ZYFLO CR tablets could significantly inhibit Critical Therapeutics ability to meet, or prevent Critical Therapeutics from meeting, commercial demand for the product.***

In the quarter ended June 30, 2008, Critical Therapeutics recorded an inventory reserve with respect to an aggregate of eight batches of ZYFLO CR that could not be released into Critical Therapeutics commercial supply chain, consisting of one batch of ZYFLO CR that did not meet Critical Therapeutics product release specifications and an additional seven batches of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. In the quarters ended December 31, 2007 and March 31, 2008, Critical Therapeutics recorded inventory reserves with respect to an aggregate of eight batches of ZYFLO CR that could not be released into Critical Therapeutics commercial supply chain because they did not meet Critical Therapeutics product release specifications. In conjunction with Critical Therapeutics three third-party manufacturers for zileuton API, tablet cores and coating and release, Critical Therapeutics has initiated an investigation to determine the cause of this issue, but the investigation is ongoing and is not yet complete. Critical Therapeutics has incurred and expects to continue to incur significant costs in connection with its investigation. To date, the investigation has not identified a clear source of the issue. In August and September 2008, Critical Therapeutics released and made available for shipment to wholesale distributors an aggregate of six batches of finished ZYFLO CR tablets that met its product release specifications. Critical Therapeutics is currently unable to accurately assess the timing and quantity of future batches of ZYFLO CR, if any, that may be released for commercial supply. If not corrected, the ongoing supply chain difficulties could prevent Critical Therapeutics from supplying any further product to its wholesale distributors. Based on its current level of sales and the release of the six batches of ZYFLO CR in August and September 2008, Critical Therapeutics estimates that wholesale distributors and retail pharmacies will have a sufficient inventory of ZYFLO CR to continue to provide product to patients through the fourth quarter of 2008.

If Critical Therapeutics investigation regarding its supply chain requires changes to its manufacturing processes or materials in order to be able to supply sufficient levels of ZYFLO CR to satisfy its commercial needs, the costs to manufacture ZYFLO CR may be significantly higher than Critical Therapeutics had anticipated. As of June 30, 2008, Critical Therapeutics has expensed $2.5 million relating to the aggregate of nine batches of ZYFLO CR that failed to meet product release specifications and the seven batches of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. In addition, Critical Therapeutics expects to incur other significant costs in connection with its investigation. If Critical Therapeutics is not able to supply ZYFLO CR at a commercially acceptable cost and level, Critical Therapeutics could experience cash flow difficulties and additional financial losses. Depending on the outcome of the investigation, Critical Therapeutics may not be able to obtain reimbursement from any of its third-party manufacturers for existing or additional batches of ZYFLO CR that do not meet Critical Therapeutics product release specifications.

Table of Contents

In April 2008, Critical Therapeutics began to reinitiate manufacture of ZYFLO in order to have a supply of ZYFLO available to reinitiate marketing and supply of ZYFLO to the market given the supply chain issues being experienced for ZYFLO CR. In September 2008, Critical Therapeutics resumed distribution of ZYFLO to help manage the potential impact to patients of supply chain issues for ZYFLO CR. However, reintroducing ZYFLO could be confusing for physicians and patients, and possibly third party wholesalers and retailers. As a result of this potential confusion relating to the reintroduction of ZYFLO to the market and ZYFLO s less convenient four times daily dosing regimen, Critical Therapeutics sales of ZYFLO will likely not meet either the level of sales of ZYFLO CR since its market launch in September 2007 or the historical level of sales of ZYFLO prior to the market launch of ZYFLO CR.

Under the merger agreement, it is a condition to Cornerstone s obligation to consummate the merger that either ZYFLO CR or ZYFLO must be available and ready for purchase by third party wholesalers or retailers during the period prior to the closing of the merger, other than during any period not exceeding 30 consecutive days. If the proposed merger with Cornerstone is not consummated, Critical Therapeutics would be subject to all of the additional risks described above under Risks Related to the Merger .

***Any failure to manage and maintain Critical Therapeutics distribution network could compromise sales of ZYFLO CR and ZYFLO and harm Critical Therapeutics business.***

Critical Therapeutics relies on third parties to distribute ZYFLO CR and ZYFLO to pharmacies. Critical Therapeutics has contracted with ICS, a third-party logistics company, to warehouse and distribute ZYFLO CR and ZYFLO to three primary wholesalers, AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation, and a number of smaller wholesalers. ICS is Critical Therapeutics exclusive supplier of commercial distribution logistics services. The wholesalers in turn distribute to chain and independent pharmacies. Sales to AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation collectively accounted for at least 95% of Critical Therapeutics annual billings for ZYFLO CR and ZYFLO during 2007. The loss of any of these wholesaler customers accounts or a material reduction in their purchases could harm Critical Therapeutics business, financial condition and results of operations.

Critical Therapeutics relies on Phoenix Marketing Group LLC, or Phoenix, to distribute product samples to Critical Therapeutics sales representatives, who in turn distribute samples to physicians and other prescribers who are authorized under state law to receive and dispense samples. This distribution network requires significant coordination with Critical Therapeutics supply chain, sales and marketing and finance organizations. Failure to maintain Critical Therapeutics contracts with ICS, the wholesalers and Phoenix, or the inability or failure of any of them to adequately perform as agreed under their respective contracts with Critical Therapeutics, could negatively impact Critical Therapeutics. Critical Therapeutics does not have its own warehouse or distribution capabilities, Critical Therapeutics lacks the resources and experience to establish any of these functions and Critical Therapeutics does not intend to establish these functions in the foreseeable future. If Critical Therapeutics was unable to replace ICS, AmerisourceBergen, Cardinal Health, McKesson Corporation or Phoenix in a timely manner in the event of a natural disaster, failure to meet FDA and other regulatory requirements, business failure, strike or any other difficulty affecting any of them, the distribution of ZYFLO CR and ZYFLO could be delayed or interrupted, which would damage Critical Therapeutics results of operations and market position. Failure to coordinate financial systems could also negatively impact Critical Therapeutics ability to accurately report and forecast product sales and fulfill Critical Therapeutics regulatory obligations. If Critical Therapeutics is unable to effectively manage and maintain its distribution network, sales of ZYFLO CR and ZYFLO could be severely compromised and Critical Therapeutics business could be harmed.

***Critical Therapeutics depends on DEY to jointly promote and market ZYFLO CR. This co-promotion arrangement may not be successful.***

Critical Therapeutics is relying on DEY to jointly promote and market ZYFLO CR. ZYFLO CR and ZYFLO are Critical Therapeutics only commercially marketed products. Critical Therapeutics ability to generate meaningful near-term revenues from product sales is substantially dependent on the success of Critical

Table of Contents

Therapeutics co-promotion arrangement with DEY. DEY initiated promotional detailing activities for ZYFLO CR in September 2007 after initiating promotional detailing for ZYFLO in April 2007.

After September 27, 2010, DEY may terminate the co-promotion agreement with six-months prior written notice. In addition, DEY has the right to terminate the co-promotion agreement with two-months, prior written notice if ZYFLO CR cumulative net sales for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than $25 million. Each party has the right to terminate the co-promotion agreement upon the occurrence of a material uncured breach by the other party. Both Critical Therapeutics and DEY have agreed to use diligent efforts to promote the applicable products in the United States during the term of the co-promotion agreement. In particular, both Critical Therapeutics and DEY have agreed to provide a minimum number of details per month for ZYFLO CR.

If DEY were to terminate or breach the co-promotion agreement, and Critical Therapeutics was unable to enter into a similar co-promotion agreement with another qualified party in a timely manner or devote sufficient financial resources or capabilities to independently promoting and marketing ZYFLO CR, Critical Therapeutics sales of ZYFLO CR would be limited and Critical Therapeutics would not be able to generate significant revenues from product sales. In addition, DEY may choose not to devote time, effort or resources to the promotion and marketing of ZYFLO CR beyond the minimum required by the terms of the co-promotion agreement. DEY is a subsidiary of Mylan. Mylan acquired DEY in October 2007 as part of its acquisition of Merck KGaA s generic business, of which DEY was a part. Critical Therapeutics cannot predict what impact Mylan s acquisition of DEY may have on Critical Therapeutics co-promotion arrangement with DEY. For example, in February 2008, Mylan announced that it is pursuing strategic alternatives for DEY, including the potential sale of the business. Any decision by DEY or Mylan not to devote sufficient resources to the co-promotion arrangement or any future reduction in efforts under the co-promotion arrangement, including as a result of the sale or potential sale of DEY by Mylan, would limit Critical Therapeutics ability to generate significant revenues from product sales. Furthermore, if DEY does not have sufficient sales capabilities, as a result of difficulty retaining or hiring sales representatives following Mylan s announcement that it is pursuing strategic alternatives for DEY or otherwise, then DEY may not be able to meet its minimum detailing obligations under the co-promotion agreement.

***Critical Therapeutics depends on MedImmune and Beckman Coulter and expects to depend on additional collaborators in the future for a portion of Critical Therapeutics revenues and to develop, conduct clinical trials with, obtain regulatory approvals for, and manufacture, market and sell some of Critical Therapeutics product candidates. These collaborations may not be successful.***

Critical Therapeutics is relying on MedImmune, Inc., a wholly owned subsidiary of AstraZeneca PLC, or MedImmune, to fund the development of and to commercialize product candidates in Critical Therapeutics HMGB1 program. Critical Therapeutics is relying on Beckman Coulter, Inc., or Beckman Coulter, to fund the development and to commercialize diagnostics in Critical Therapeutics HMGB1 program. All of Critical Therapeutics revenues prior to October 2005, when Critical Therapeutics commercially launched ZYFLO, were derived from Critical Therapeutics collaboration agreements with MedImmune and Beckman Coulter. Additional payments due to Critical Therapeutics under the collaboration agreements with MedImmune and Beckman Coulter are generally based on the achievement of specific development and commercialization milestones that may not be met. In addition, the collaboration agreements entitle Critical Therapeutics to royalty payments that are based on the sales of products developed and marketed through the collaborations. These future royalty payments may not materialize or may be less than expected if the related products are not successfully developed or marketed or if Critical Therapeutics is forced to license intellectual property to continue to generate revenues for Critical Therapeutics.

Critical Therapeutics collaboration agreement with MedImmune generally is terminable by MedImmune at any time upon six-months notice or upon Critical Therapeutics material uncured breach of the agreement. In

39

Table of Contents

addition, Critical Therapeutics and MedImmune agreed to work exclusively in the development and commercialization of HMGB1-inhibiting products for a period of four years, and, after such time, Critical Therapeutics has agreed to work exclusively with MedImmune in the development of HMGB1-inhibiting products for the remaining term of the agreement. If MedImmune were to terminate or breach this arrangement, and Critical Therapeutics was unable to enter into a similar collaboration agreement with another qualified third party in a timely manner or devote sufficient financial resources or capabilities to continue development and commercialization on its own, the development and commercialization of Critical Therapeutics HMGB1 program likely would be delayed, curtailed or terminated. The delay, curtailment or termination of Critical Therapeutics HMGB1 program could significantly harm Critical Therapeutics future prospects.

Critical Therapeutics license agreement with Beckman Coulter generally is terminable by Beckman Coulter on 90-days written notice. Each party has the right to terminate the license agreement upon the occurrence of a material uncured breach by the other party. If Beckman Coulter were to terminate or breach Critical Therapeutics arrangement, and Critical Therapeutics was unable to enter into a similar agreement with another qualified third party in a timely manner or devote sufficient financial resources or capabilities to continue development and commercialization on its own, the development and commercialization of a diagnostic based on the detection of HMGB1 likely would be delayed, curtailed or terminated.

In addition, Critical Therapeutics collaborations with MedImmune and Beckman Coulter and any future collaborative arrangements that Critical Therapeutics enters into with third parties may not be scientifically or commercially successful. Factors that may affect the success of Critical Therapeutics collaborations include the following:

- Critical Therapeutics collaborators may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive with the product on which they are collaborating with Critical Therapeutics or that could affect Critical Therapeutics collaborators commitment to Critical Therapeutics;

- reductions in marketing or sales efforts or a discontinuation of marketing or sales of Critical Therapeutics products by Critical Therapeutics collaborators would reduce Critical Therapeutics revenues, which Critical Therapeutics expects will be based on a percentage of net sales by collaborators;

- Critical Therapeutics collaborators may terminate their collaborations with Critical Therapeutics, which could make it difficult for Critical Therapeutics to attract new collaborators or adversely affect how Critical Therapeutics is perceived in the business and financial communities;

- Critical Therapeutics collaborators may not devote sufficient time and resources to any collaboration with Critical Therapeutics, which could prevent Critical Therapeutics from realizing the potential commercial benefits of that collaboration; and

- Critical Therapeutics collaborators may pursue higher priority programs or change the focus of their development programs, which could affect their commitments to Critical Therapeutics.

In June 2007, AstraZeneca PLC completed its acquisition of MedImmune and MedImmune became a wholly owned subsidiary of AstraZeneca. Critical Therapeutics cannot predict what impact this transaction may have on Critical Therapeutics HMGB1 collaboration with MedImmune. If MedImmune does not devote sufficient time and resources to Critical Therapeutics collaboration or changes the focus of its programs, it could delay or prevent the achievement of clinical, regulatory and commercial milestones and prevent Critical Therapeutics from realizing the potential commercial benefits of the collaboration.

Critical Therapeutics may seek to enter into collaboration agreements with other parties in the future that relate to Critical Therapeutics other product candidates, and Critical Therapeutics is likely to have similar risks with regard to any such future collaborations.

Table of Contents

***SetPoint may not be successful in developing a product under the patent rights and know-how that Critical Therapeutics licensed to SetPoint relating to the mechanical and electrical stimulation of the vagus nerve.***

Critical Therapeutics has licensed to SetPoint Medical Corporation (formerly known as Innovative Metabolics, Inc.), or SetPoint, patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. SetPoint is an early-stage company. Critical Therapeutics is not involved in SetPoint s efforts to develop and commercialize a medical device based on the intellectual property that Critical Therapeutics licensed to SetPoint. Critical Therapeutics will receive additional payments under the SetPoint license only if SetPoint is successful in achieving full regulatory approval of such a device or receives a royalty, fee or other payment from a third party in connection with a sublicense of its rights under Critical Therapeutics license agreement.

***If Critical Therapeutics is unable to enter into additional collaboration agreements, Critical Therapeutics may not be able to continue development of its product candidates.***

Critical Therapeutics drug development programs and potential commercialization of Critical Therapeutics product candidates will require substantial additional cash to fund expenses to be incurred in connection with these activities. Critical Therapeutics may seek to enter into additional collaboration agreements with pharmaceutical or biotechnology companies to fund all or part of the costs of drug development and commercialization of product candidates. For example, Critical Therapeutics has determined as a strategic matter to seek to enter into collaboration arrangements with respect to the development of its alpha-7 product candidates and its zileuton injection product candidate. Critical Therapeutics is not currently actively engaged in negotiations with respect to and has no current understandings, agreements or commitments for any such collaboration arrangements. Critical Therapeutics faces, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaboration agreements are complex and time consuming to negotiate, document and implement. Critical Therapeutics may not be able to enter into future collaboration agreements, and the terms of the collaboration agreements, if any, may not be favorable to Critical Therapeutics. If Critical Therapeutics is not successful in its efforts to enter into a collaboration arrangement with respect to a product candidate, Critical Therapeutics may not have sufficient funds to develop any of its product candidates internally. If Critical Therapeutics does not have sufficient funds to develop its product candidates, Critical Therapeutics will not be able to bring these product candidates to market and generate revenue. In addition, Critical Therapeutics inability to enter into collaboration agreements could delay or preclude the development, manufacture and/or commercialization of a product candidate and could have a material adverse effect on Critical Therapeutics financial condition and results of operations because:

- Critical Therapeutics may be required to expend its own funds to advance the product candidate to commercialization;
- revenue from product sales could be delayed; or
- Critical Therapeutics may elect not to develop or commercialize the product candidate.

***Critical Therapeutics plans to rely significantly on third parties to market some product candidates, and these third parties may not successfully commercialize these product candidates.***

For product candidates with large target physician markets, Critical Therapeutics plans to rely significantly on sales, marketing and distribution arrangements with third parties. For example, Critical Therapeutics relies on MedImmune for the commercialization of any anti-HMGB1 products that are developed under the exclusive license and collaboration agreement between the parties, and Critical Therapeutics plans to rely on Beckman Coulter for the commercialization of any diagnostic assay for HMGB1. Critical Therapeutics may not be successful in entering into additional marketing arrangements in the future and, even if successful, Critical Therapeutics may not be able to enter

into these arrangements on terms that are favorable to Critical Therapeutics. In addition, Critical Therapeutics may have limited or no control over the sales, marketing and distribution activities of these third parties. If these third parties are not successful in commercializing the products covered by these arrangements, Critical Therapeutics future revenues may suffer.

Table of Contents

**Risks Relating to Critical Therapeutics Financial Results and Need for Additional Financing**

***Critical Therapeutics has incurred losses since inception and Critical Therapeutics anticipates that it will continue to incur losses for the foreseeable future. If Critical Therapeutics does not generate significant revenues, Critical Therapeutics will not be able to achieve profitability.***

Critical Therapeutics has experienced significant operating losses in each year since its inception in 2000. Critical Therapeutics had net losses of $37.0 million in the year ended December 31, 2007 and $48.8 million in the year ended December 31, 2006. Critical Therapeutics had net losses of $17.4 million in the six months ended June 30, 2008 and $17.6 million in the six months ended June 30, 2007. As of June 30, 2008, Critical Therapeutics had an accumulated deficit of approximately $209 million. Critical Therapeutics recorded revenue from the sale of ZYFLO and ZYFLO CR of $11.0 million for the year ended December 31, 2007 and $7.2 million for the six months ended June 30, 2008. Critical Therapeutics has not recorded revenue from any products other than ZYFLO CR and ZYFLO. Critical Therapeutics expects that it will continue to incur substantial losses for the foreseeable future as it spends significant amounts to fund its development and commercialization efforts. Critical Therapeutics expects that the losses that it incurs will fluctuate from quarter to quarter and that these fluctuations may be substantial. Critical Therapeutics will need to generate significant revenues to achieve profitability. Until Critical Therapeutics is able to generate such revenues, it will not be profitable and will need to raise substantial additional capital to fund its operations.

***Critical Therapeutics will require substantial additional capital to fund its operations. If additional capital is not available, Critical Therapeutics may need to delay, limit or eliminate its development and commercialization efforts.***

Critical Therapeutics expects to devote substantial resources to support ongoing sales and marketing efforts for ZYFLO CR and to fund the development of its other product candidates. Critical Therapeutics funding requirements will depend on numerous factors, including:

- the ongoing costs of sales and marketing of ZYFLO CR;
- the amount and timing of sales and returns of ZYFLO CR and ZYFLO;
- the costs of ongoing manufacturing activities for ZYFLO CR and ZYFLO;
- the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals for Critical Therapeutics product candidates;
- the timing, receipt and amount of milestone and other payments, if any, from DEY, MedImmune, Beckman Coulter, SetPoint or future collaborators or licensees;
- the timing, receipt and amount of sales and royalties, if any, from Critical Therapeutics product candidates;
- continued progress in Critical Therapeutics research and development programs, as well as the magnitude of these programs, including milestone payments to third parties under Critical Therapeutics license agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the cost of obtaining and maintaining licenses to use patented technologies;
- potential acquisition or in-licensing of other products or technologies;

Critical Therapeutics ability to establish and maintain additional collaborative or co-promotion arrangements; and

the ongoing time and costs involved in corporate governance requirements, including work related to compliance with the Sarbanes-Oxley Act.

Other than payments that Critical Therapeutics may receive from its collaborations with MedImmune and Beckman Coulter, sales of ZYFLO CR and ZYFLO represent Critical Therapeutics only sources of cash flow and revenue. Critical Therapeutics believes that its ability to access external funds will depend upon market acceptance

Table of Contents

of ZYFLO CR, the success of Critical Therapeutics other preclinical and clinical development programs, the receptivity of the capital markets to financings by biopharmaceutical companies, Critical Therapeutics ability to enter into additional strategic collaborations with corporate and academic collaborators and the success of such collaborations.

The extent of Critical Therapeutics future capital requirements is difficult to assess and will depend largely on Critical Therapeutics ability to successfully commercialize ZYFLO CR. Based on Critical Therapeutics current operating plans, Critical Therapeutics believes that its available cash and cash equivalents and anticipated cash received from product sales will be sufficient to fund anticipated levels of operations into the first quarter of 2009.

Critical Therapeutics net cash used for operating activities was $14.4 million for the year ended December 31, 2007 and $23.2 million for the six months ended June 30, 2008. Critical Therapeutics had minimal capital expenditures for the six months ended June 30, 2008. If Critical Therapeutics existing resources are insufficient to satisfy its liquidity requirements or if Critical Therapeutics acquires or licenses rights to additional products or product candidates, Critical Therapeutics may need to raise additional external funds through collaborative arrangements and public or private financings. Under Critical Therapeutics merger agreement with Cornerstone, any financing transaction would require Cornerstone s consent. Additional financing may not be available to Critical Therapeutics on acceptable terms or at all. If Critical Therapeutics is unable to obtain funding on a timely basis, Critical Therapeutics may be required to significantly delay, limit or eliminate one or more of its research, development or commercialization programs, which could harm its financial condition and operating results.

***Even if Critical Therapeutics is able to obtain additional capital to fund its operations, the terms may not be favorable to Critical Therapeutics or its stockholders.***

If Critical Therapeutics future capital requirements require it to raise additional external funds, collaborative arrangements or public or private financings may only be available on unfavorable terms. For example, arrangements with collaborators or others may require Critical Therapeutics to relinquish valuable rights to its technologies, product candidates or products, which Critical Therapeutics would otherwise pursue on its own.
In addition, debt financing, if available, may involve agreements that include covenants limiting or restricting Critical Therapeutics ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If Critical Therapeutics raises additional funds by issuing equity securities, stockholders will experience dilution. Furthermore, any debt financing or additional equity that Critical Therapeutics raises may contain terms, such as liquidation and other preferences, that are not favorable to Critical Therapeutics or its stockholders.

***The audit report issued by Critical Therapeutics independent registered public accounting firm stating that there is substantial doubt about Critical Therapeutics ability to continue as a going concern could make it more difficult for Critical Therapeutics to obtain additional financing.***

As a result of Critical Therapeutics recurring losses from operations, accumulated deficit and Critical Therapeutics expectation that it will incur substantial additional operating costs for the foreseeable future, as discussed in Note 1 to Critical Therapeutics consolidated financial statements beginning on page F-7 of this proxy statement/prospectus, there is substantial doubt about Critical Therapeutics ability to continue as a going concern. Critical Therapeutics ability to continue as a going concern will require Critical Therapeutics to obtain additional financing to fund its operations. Critical Therapeutics has prepared its financial statements on the assumption that it will continue as a going concern, which contemplates the realization of assets and discharge of liabilities in the normal course of business. Doubt about its ability to continue as a going concern may make it more difficult for Critical Therapeutics to obtain financing for the continuation of its operations and could result in the loss of confidence by investors, suppliers and employees.

43

Table of Contents

***If the estimates Critical Therapeutics makes, or the assumptions on which Critical Therapeutics relies, in preparing its financial statements prove inaccurate, Critical Therapeutics actual results may vary from those reflected in its projections.***

Critical Therapeutics financial statements have been prepared in accordance with GAAP. The preparation of these financial statements requires Critical Therapeutics to make estimates and judgments that affect the reported amounts of Critical Therapeutics assets, liabilities, revenues and expenses, the amounts of charges accrued by Critical Therapeutics and related disclosure of contingent assets and liabilities. Critical Therapeutics bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. For example, Critical Therapeutics reserve for potential returns for ZYFLO CR and ZYFLO is based on its historical experience of product returns for ZYFLO and other factors that could significantly impact expected returns. Critical Therapeutics cannot assure you, however, that its estimates, or the assumptions underlying them, will be correct. If Critical Therapeutics estimates are inaccurate, this could adversely affect its stock price.

**Risks Relating to Intellectual Property and Licenses**

***If Critical Therapeutics or its licensors are not able to obtain and enforce patent and other intellectual property protection for Critical Therapeutics discoveries or discoveries Critical Therapeutics has in-licensed, Critical Therapeutics ability to prevent third parties from using Critical Therapeutics inventions and proprietary information will be limited and Critical Therapeutics may not be able to operate its business profitably.***

Critical Therapeutics success depends, in part, on its ability to protect proprietary products, methods and technologies that Critical Therapeutics invents, develops or licenses under the patent and other intellectual property laws of the United States and other countries, so that Critical Therapeutics can prevent others from using its inventions and proprietary information. The composition of matter patent for zileuton in the United States will expire in December 2010. The patent for ZYFLO CR, which relates only to the controlled-release technology used to control the release of zileuton, will expire in June 2012. Critical Therapeutics is exploring strategies to extend and expand the patent protection for its zileuton products, but Critical Therapeutics may not be able to obtain additional patent protection.

Because certain U.S. patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date that will not be filed in foreign countries and for which a request for non-publication is filed, and because even patent applications for which no request for non-publication is made are not published until approximately 18 months after filing, third parties may have already filed patent applications for technology covered by Critical Therapeutics pending patent applications, and Critical Therapeutics patent applications may not have priority over any such patent applications of others. There may also be prior art that may prevent allowance of Critical Therapeutics patent applications or enforcement of Critical Therapeutics or Critical Therapeutics licensors issued patents.

Critical Therapeutics patent strategy depends on Critical Therapeutics ability to rapidly identify and seek patent protection for Critical Therapeutics discoveries. This process is expensive and time consuming, and Critical Therapeutics may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely or successful manner. Moreover, the mere issuance of a patent does not guarantee that it is valid or enforceable. As a result, even if Critical Therapeutics obtains patents, they may not be valid or enforceable against third parties.

Critical Therapeutics pending patent applications and those of its licensors may not result in issued patents. In addition, the patent positions of pharmaceutical or biotechnology companies, including Critical Therapeutics, are generally uncertain and involve complex legal and factual considerations. The standards that the U.S. Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and

can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, Critical Therapeutics does not know the degree of future protection for its proprietary rights or the breadth of claims that will be allowed in any patents issued to Critical Therapeutics or to others with respect to its products in the future.

Table of Contents

Critical Therapeutics also relies on trade secrets, know-how and technology, which are not protected by patents, to maintain its competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to, or independently developed by, a competitor, any competitive advantage that Critical Therapeutics may have had in the development or commercialization of its product candidates would be minimized or eliminated.

Critical Therapeutics confidentiality agreements with its current and potential collaborators, employees, consultants, strategic partners, outside scientific collaborators and sponsored researchers and other advisors may not effectively prevent disclosure of Critical Therapeutics confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of Critical Therapeutics proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect Critical Therapeutics competitive business position.

***Litigation regarding patents, patent applications and other proprietary rights is expensive and time consuming. If Critical Therapeutics is unsuccessful in litigation or other adversarial proceedings concerning patents or patent applications, Critical Therapeutics may not be able to protect its products from competition or Critical Therapeutics may be precluded from selling its products. If Critical Therapeutics is involved in such litigation, it could cause delays in, or prevent Critical Therapeutics from, bringing products to market and harm Critical Therapeutics ability to operate.***

Critical Therapeutics success will depend in part on its ability to uphold and enforce the patents or patent applications owned or co-owned by Critical Therapeutics or licensed to Critical Therapeutics that cover its products and product candidates. Litigation, interferences or other adversarial proceedings relating to Critical Therapeutics patents or patent applications could take place in the United States or foreign courts or in the United States or foreign patent offices or other administrative agencies. Proceedings involving Critical Therapeutics patents or patent applications could result in adverse decisions regarding:

- the patentability of Critical Therapeutics applications, including those relating to Critical Therapeutics products; or
- the enforceability, validity or scope of protection offered by Critical Therapeutics patents, including those relating to Critical Therapeutics products.

These proceedings are costly and time consuming. Critical Therapeutics may not have sufficient resources to bring these actions or to bring such actions to a successful conclusion. Even if Critical Therapeutics is successful in these proceedings, Critical Therapeutics may incur substantial cost and divert the time and attention of Critical Therapeutics management and scientific personnel in pursuit of these proceedings, which could have a material adverse effect on Critical Therapeutics business.

If it is determined that Critical Therapeutics does infringe a patent right of another, Critical Therapeutics may be required to seek a license, defend an infringement action or challenge the validity of the patent in court. In addition, if Critical Therapeutics is not successful in infringement litigation brought against Critical Therapeutics and Critical Therapeutics does not license or develop non-infringing technology, Critical Therapeutics may:

- incur substantial monetary damages, potentially including treble damages, if Critical Therapeutics is found to have willfully infringed on such parties patent rights;
- encounter significant delays in bringing Critical Therapeutics product candidates to market; or

be precluded from participating in the manufacture, use or sale of Critical Therapeutics products or methods of treatment.

If any parties should successfully claim that Critical Therapeutics creation or use of proprietary technologies infringes upon their intellectual property rights, Critical Therapeutics might be forced to pay damages. In addition to any damages Critical Therapeutics might have to pay, a court could require Critical Therapeutics to stop the infringing activity. Moreover, any legal action against Critical Therapeutics or Critical Therapeutics collaborators claiming damages and seeking to enjoin commercial activities relating to the affected products and

Table of Contents

processes could, in addition to subjecting Critical Therapeutics to potential liability for damages, require Critical Therapeutics or Critical Therapeutics collaborators to obtain a license in order to continue to manufacture or market the affected products and processes. Any such required license may not be made available on commercially acceptable terms, if at all. In addition, some licenses may be non-exclusive and, therefore, Critical Therapeutics competitors may have access to the same technology licensed to Critical Therapeutics.

If Critical Therapeutics fails to obtain a required license or is unable to design around a patent, Critical Therapeutics may be unable to effectively market some of its technology or products, which could limit Critical Therapeutics ability to generate revenues or achieve profitability and possibly prevent Critical Therapeutics from generating revenue sufficient to sustain its operations. In addition, Critical Therapeutics MedImmune collaboration agreement provides that a portion of the royalties payable to Critical Therapeutics by MedImmune for licenses to Critical Therapeutics intellectual property may be offset by amounts paid by MedImmune to third parties who have competing or superior intellectual property positions in the relevant fields, which could result in significant reductions in Critical Therapeutics revenues.

Some of Critical Therapeutics competitors may be able to sustain the costs of complex intellectual property litigation more effectively than Critical Therapeutics can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit Critical Therapeutics ability to continue its operations.

***Critical Therapeutics in-licenses a significant portion of its principal proprietary technologies, and if Critical Therapeutics fails to comply with its obligations under any of the related agreements, Critical Therapeutics could lose license rights that are necessary to develop and market its zileuton products, its HMGB1 products and some of its other product candidates.***

Critical Therapeutics is a party to a number of licenses that give Critical Therapeutics rights to third-party intellectual property that is necessary for Critical Therapeutics business. In fact, Critical Therapeutics acquired the rights to each of its product candidates under licenses with third parties. These licenses impose various development, commercialization, funding, royalty, diligence and other obligations on Critical Therapeutics. If Critical Therapeutics breaches these obligations, Critical Therapeutics licensors may have the right to terminate the licenses or render the licenses non-exclusive, which would result in Critical Therapeutics being unable to develop, manufacture and sell products that are covered by the licensed technology, or at least to do so on an exclusive basis.

**Risk Relating to Regulatory and Legal Compliance by Critical Therapeutics**

***Critical Therapeutics will spend considerable time and money complying with federal and state laws and regulations, and, if Critical Therapeutics is unable to fully comply with such laws and regulations, Critical Therapeutics could face substantial penalties.***

Critical Therapeutics is subject to extensive regulation by federal and state governments. The laws that directly or indirectly affect Critical Therapeutics business include, but are not limited to, the following:

- federal Medicare and Medicaid anti-kickback laws, which prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- other Medicare laws and regulations that establish the requirements for coverage and payment for Critical Therapeutics products, including the amount of such payments;

the federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any health care benefit program, including private payors and, further, requires Critical Therapeutics to comply with standards regarding privacy and security of individually identifiable health information and conduct certain electronic transactions using standardized code sets;

Table of Contents

the federal False Statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;

the federal Food, Drug, and Cosmetic Act, or FDCA, which regulates development, manufacturing, labeling, marketing, distribution and sale of prescription drugs and medical devices;

the federal Prescription Drug Marketing Act of 1987, which regulates the distribution of drug samples to physicians and other prescribers who are authorized under state law to receive and dispense drug samples;

state and foreign law equivalents of the foregoing;

state food and drug laws, pharmacy acts and state pharmacy board regulations, which govern the sale, distribution, use, administration and prescribing of prescription drugs; and

state laws that prohibit the practice of medicine by non-physicians and fee-splitting arrangements between physicians and non-physicians, as well as state law equivalents to the federal Medicare and Medicaid anti-kickback laws, which may not be limited to government reimbursed items or services.

On January 1, 2006, Critical Therapeutics became a participant in the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as amended, effective in 1993. Under the Medicaid rebate program, Critical Therapeutics pays a rebate for each unit of Critical Therapeutics product reimbursed by Medicaid. The amount of the rebate for each product is set by law. Critical Therapeutics is also required to pay certain statutorily defined rebates on Medicaid purchases for reimbursement on prescription drugs under state Medicaid plans. Both the federal government and state governments have initiated investigations into the rebate practices of many pharmaceutical companies to ensure compliance with these rebate programs. Any investigation of Critical Therapeutics rebate practices could be costly, could divert the attention of Critical Therapeutics management and could damage Critical Therapeutics reputation.

If Critical Therapeutics past or present operations are found to be in violation of any of the laws described above or other laws or governmental regulations to which Critical Therapeutics or its customers are subject, Critical Therapeutics may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from Medicare and Medicaid programs and curtailment or restructuring of Critical Therapeutics operations. Similarly, if Critical Therapeutics customers are found non compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on Critical Therapeutics. In addition, if Critical Therapeutics is required to obtain permits or licenses under these laws that Critical Therapeutics does not already possess, Critical Therapeutics may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of Critical Therapeutics operations would adversely affect its ability to operate its business and its financial results. Health care fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims of a violation. The risk of Critical Therapeutics being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change.

If Critical Therapeutics promotional activities fail to comply with the FDA s regulations or guidelines, Critical Therapeutics may be subject to enforcement action by the FDA. For example, Critical Therapeutics received a warning letter from the FDA in November 2005 relating to certain promotional material that included an illustration of the mechanism of action for ZYFLO. The FDA asserted that the promotional material incorporating the illustration

was false or misleading because it presented efficacy claims for ZYFLO, but failed to contain fair balance by not communicating the risks associated with its use and failing to present the approved indication for ZYFLO. In response to the warning letter, and as requested by the FDA, Critical Therapeutics stopped disseminating the promotional material containing the mechanism of action and Critical Therapeutics provided a written response to the FDA. As part of Critical Therapeutics response, Critical Therapeutics provided a description of its plan to disseminate corrective messages about the promotional material to those who received this material. Critical Therapeutics revised the promotional material containing the mechanism of action to address the FDA s concerns regarding fair balance. If Critical Therapeutics

Table of Contents

promotional activities fail to comply with the FDA s regulations or guidelines, Critical Therapeutics could be subject to additional regulatory actions by the FDA, including product seizure, injunctions, and other penalties and Critical Therapeutics reputation and the reputation of ZYFLO CR in the market could be harmed.

Any action against Critical Therapeutics for violation of these laws, even if Critical Therapeutics successfully defends against it, could cause Critical Therapeutics to incur significant legal expenses, divert Critical Therapeutics management s attention from operating Critical Therapeutics business and damage Critical Therapeutics reputation or Critical Therapeutics brands. If there is a change in law, regulation or administrative or judicial interpretations, Critical Therapeutics may have to change or discontinue its business practices or its existing business practices could be challenged as unlawful, which could materially harm its business, financial condition and results of operations.

***State pharmaceutical marketing and promotional compliance and reporting requirements may expose Critical Therapeutics to regulatory and legal action by state governments or other governmental authorities.***

In recent years, several states, including California, Maine, Minnesota, Nevada, New Mexico, Vermont and West Virginia, as well as the District of Columbia, have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs and file periodic reports with the state on sales, marketing, pricing, reporting pricing and other activities. For example, a California statute effective July 1, 2005 requires pharmaceutical companies to adopt and post on their public web site a comprehensive compliance program that complies with the Pharmaceutical Research and Manufacturers of America *Code on Interactions with Healthcare Professionals* and the Office of Inspector General of the Department of Health and Human Services *Compliance Program Guidance for Pharmaceutical Manufacturers.* In addition, such compliance program must establish a specific annual dollar limit on gifts or other items given to individual healthcare professionals in California.

Maine, Minnesota, New Mexico, Nevada, Vermont, West Virginia and the District of Columbia have also enacted statutes of varying scope that impose reporting and disclosure requirements upon pharmaceutical companies pertaining to drug pricing and payments and costs associated with pharmaceutical marketing, advertising and promotional activities, as well as restrictions upon the types of gifts that may be provided to health care practitioners. Similar legislation is being considered in a number of other states. Many of these requirements are new and uncertain, and available guidance is limited. Critical Therapeutics is in the process of identifying the universe of state laws applicable to pharmaceutical companies and is taking steps to ensure that Critical Therapeutics comes into compliance with all such laws. Unless and until Critical Therapeutics is in full compliance with these laws, Critical Therapeutics could face enforcement action and fines and other penalties, and could receive adverse publicity, all of which could materially harm Critical Therapeutics business.

***Recently enacted legislation may make it more difficult and costly for Critical Therapeutics to obtain regulatory approval of its product candidates and to produce, market and distribute its existing products.***

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007, or the FDAAA. The FDAAA grants a variety of new powers to the FDA, many of which are aimed at assuring drug safety and monitoring the safety of drug products after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While Critical Therapeutics expects the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as Critical Therapeutics business, will become more clear. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products.

Table of Contents

***Critical Therapeutics corporate compliance and corporate governance programs cannot guarantee that Critical Therapeutics is in compliance with all potentially applicable regulations.***

The development, manufacturing, pricing, marketing, sales and reimbursement of ZYFLO CR and ZYFLO and Critical Therapeutics product candidates, together with Critical Therapeutics general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. Critical Therapeutics is a relatively small company and had approximately 42 employees as of September 15, 2008. Critical Therapeutics relies heavily on third parties to conduct many important functions. While Critical Therapeutics has developed and instituted a corporate compliance program based on what Critical Therapeutics believes are the current best practices and continues to update the program in response to newly implemented and changing regulatory requirements, it is possible that Critical Therapeutics may not be in compliance with all potentially applicable regulations. If Critical Therapeutics fails to comply with any of these regulations, Critical Therapeutics could be subject to a range of regulatory actions, including significant fines, litigation or other sanctions. Any action against Critical Therapeutics for a violation of these regulations, even if Critical Therapeutics successfully defends against it, could cause Critical Therapeutics to incur significant legal expenses, divert Critical Therapeutics management s attention and harm Critical Therapeutics reputation.

As a publicly traded company, Critical Therapeutics is subject to significant legal and regulatory requirements, including the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and related regulations, some of which have either only recently become applicable to Critical Therapeutics or are subject to change. For example, Critical Therapeutics is incurring additional expenses and devoting significant management time and attention to evaluating its internal control systems to allow Critical Therapeutics management to report on, and Critical Therapeutics independent registered public accounting firm to attest to, Critical Therapeutics internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. If the controls and procedures that Critical Therapeutics has implemented do not comply with all of the relevant rules and regulations of the SEC and NASDAQ, Critical Therapeutics may be subject to sanctions or investigation by regulatory authorities, including the SEC or NASDAQ. This type of action could adversely affect Critical Therapeutics financial results or investors confidence in Critical Therapeutics and Critical Therapeutics ability to access the capital markets and could result in the delisting of Critical Therapeutics common stock from NASDAQ. If Critical Therapeutics fails to develop and maintain adequate controls and procedures, Critical Therapeutics may be unable to provide the required financial information in a timely and reliable manner, which could cause a decline in Critical Therapeutics stock price.

***Critical Therapeutics sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement could result in decreased use or sales of Critical Therapeutics products.***

Critical Therapeutics sales of ZYFLO CR and ZYFLO are, and any future sales of Critical Therapeutics product candidates will be, dependent, in part, on the availability of reimbursement from third-party payors such as state and federal governments, under programs such as Medicare and Medicaid, and private insurance plans. There have been, there are and Critical Therapeutics expects there will continue to be, state and federal legislative and administrative proposals that could limit the amount that state or federal governments will pay to reimburse the cost of pharmaceutical and biologic products. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, was signed into law in December 2003. Legislative or administrative acts that reduce reimbursement for Critical Therapeutics products could adversely impact Critical Therapeutics business. In addition, Critical Therapeutics believes that private insurers, such as MCOs, may adopt their own reimbursement reductions in response to legislation. Any reduction in reimbursement for Critical Therapeutics products could materially harm Critical Therapeutics results of operations. In addition, Critical Therapeutics believes that the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of Critical Therapeutics products, which may adversely impact Critical Therapeutics product sales. Furthermore, when a new drug product is approved, governmental and private reimbursement for that product, and the amount for which that product will be

reimbursed, are uncertain. Critical Therapeutics cannot predict the availability or amount of

Table of Contents

reimbursement for Critical Therapeutics product candidates and current reimbursement policies for marketed products may change at any time.

The MMA established a prescription drug benefit that became effective in 2006 for all Medicare beneficiaries. Critical Therapeutics cannot be certain that ZYFLO CR, ZYFLO or any of Critical Therapeutics product candidates still in development, will be included in the Medicare prescription drug benefit. Even if Critical Therapeutics products are included, the MCOs, health maintenance organizations, or HMOs, preferred provider organizations, or PPOs, and private health plans that administer the Medicare drug benefit have the ability to negotiate price and demand discounts from pharmaceutical and biotechnology companies that may implicitly create price controls on prescription drugs. On the other hand, the drug benefit may increase the volume of pharmaceutical drug purchases, offsetting at least in part these potential price discounts. In addition, MCOs, HMOs, PPOs, health care institutions and other government agencies continue to seek price discounts. Because MCOs, HMOs, PPOs and private health plans will administer the Medicare drug benefit, managed care and private health plans will influence prescription decisions for a larger segment of the population. In addition, certain states have proposed and certain other states have adopted various programs to control prices for senior citizens and drug programs for people with low incomes, including price or patient reimbursement constraints, restrictions on access to certain products, and bulk purchasing of drugs.

If Critical Therapeutics succeeds in bringing products in addition to ZYFLO CR and ZYFLO to the market, these products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow Critical Therapeutics to sell its product candidates on a competitive basis to a sufficient patient population. Because Critical Therapeutics product candidates are in the development stage, Critical Therapeutics is unable at this time to determine the cost-effectiveness of these product candidates. Critical Therapeutics may need to conduct expensive pharmacoeconomic trials in order to demonstrate their cost-effectiveness. Sales of prescription drugs are highly dependent on the availability and level of reimbursement to the consumer from third-party payors, such as government and private insurance plans. These third-party payors frequently require that drug companies provide them with predetermined discounts or rebates from list prices, and third-party payors are increasingly challenging the prices charged for medical products. Because Critical Therapeutics product candidates are in the development stage, Critical Therapeutics does not know the level of reimbursement, if any, it will receive for those product candidates if they are successfully developed. If the reimbursement Critical Therapeutics receives for any of its product candidates is inadequate in light of Critical Therapeutics development and other costs, Critical Therapeutics ability to realize profits from the affected product candidate would be limited. If reimbursement for Critical Therapeutics marketed products changes adversely or if Critical Therapeutics fails to obtain adequate reimbursement for its other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of Critical Therapeutics products or cause Critical Therapeutics to reduce the price of its products.

**Risks Relating to Development, Clinical Testing and Regulatory Approval of Critical Therapeutics Product Candidates.**

***Critical Therapeutics may not be successful in its efforts to advance and expand its portfolio of product candidates.***

An element of Critical Therapeutics strategy is to develop and commercialize product candidates that address large unmet medical needs. Critical Therapeutics seeks to do so through:

- preclinical studies to evaluate product candidates;

- sponsored research programs with academic and other research institutions and individual doctors, chemists and researchers; and

collaborations with other pharmaceutical or biotechnology companies with complementary clinical development or commercialization capabilities or capital to assist in funding product development and commercialization.

In addition, subject to having sufficient cash and other resources to develop or commercialize additional products, Critical Therapeutics may seek to in-license or acquire product candidates or approved products. However, Critical Therapeutics may be unable to license or acquire suitable product candidates or products

Table of Contents

from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is competitive. A number of more established companies are also pursuing strategies to license or acquire products. These established companies may have a competitive advantage over Critical Therapeutics due to their size, cash resources or greater clinical development and commercialization capabilities. Other factors that may prevent Critical Therapeutics from licensing or otherwise acquiring suitable product candidates or approved products include the following:

- Critical Therapeutics may be unable to license or acquire the relevant technology on terms that would allow Critical Therapeutics to make an appropriate return from the product;
- companies that perceive Critical Therapeutics as a competitor may be unwilling to assign or license their product rights to Critical Therapeutics;
- Critical Therapeutics may be unable to identify suitable products or product candidates within Critical Therapeutics areas of expertise; and
- Critical Therapeutics may have inadequate cash resources or may be unable to access public or private financing to obtain rights to suitable products or product candidates from third parties.

If Critical Therapeutics is unable to develop suitable potential product candidates through Critical Therapeutics preclinical studies or sponsored research programs or by obtaining rights from third parties, Critical Therapeutics will not be able to increase its revenues in future periods, which could result in significant harm to Critical Therapeutics financial position and adversely impact Critical Therapeutics stock price.

***If Critical Therapeutics does not obtain the regulatory approvals or clearances required to market and sell Critical Therapeutics product candidates under development, Critical Therapeutics business may be unsuccessful.***

Neither Critical Therapeutics nor any of its collaborators may market any of Critical Therapeutics products or its product candidates under development in the United States, Europe or in any other country without marketing approval from the FDA or the equivalent foreign regulatory agency. ZYFLO CR and ZYFLO are currently Critical Therapeutics only commercial products and can only be marketed in the United States.

The regulatory process to obtain marketing approval or clearance for a new drug or biologic takes many years, requires expenditures of substantial resources, is uncertain and is subject to unanticipated delays. Adverse side effects of a product candidate in a clinical trial could result in the FDA or foreign regulatory authorities refusing to approve or clear a particular product candidate for any or all indications for use.

The FDA and foreign regulatory agencies have substantial discretion in the drug approval process and can deny, delay or limit approval of a product candidate for a variety of reasons. If Critical Therapeutics does not receive the required regulatory approval or clearance to market any of its product candidates under development, Critical Therapeutics ability to generate product revenue and achieve profitability, Critical Therapeutics reputation and Critical Therapeutics ability to raise additional capital will be materially impaired.

***Critical Therapeutics limited experience in obtaining regulatory approvals could delay, limit or prevent such approvals for its product candidates.***

Critical Therapeutics has only limited experience in preparing applications and obtaining regulatory approvals and clearances for its product candidates. Since inception, Critical Therapeutics has received approval to market only two drugs in the United States, ZYFLO CR and ZYFLO. Critical Therapeutics limited experience in this regard could

delay or limit approval of its product candidates if it is unable to effectively manage the applicable regulatory process with either the FDA or foreign regulatory authorities. In addition, significant errors or ineffective management of the regulatory process could prevent approval of a product candidate, especially given the substantial discretion that the FDA and foreign regulatory authorities have in this process.

***If clinical trials for Critical Therapeutics product candidates are not successful, Critical Therapeutics may not be able to develop, obtain regulatory approval for and commercialize these product candidates successfully.***

Critical Therapeutics product candidates, such as zileuton injection and product candidates directed toward the body s inflammatory response, including in its alpha-7 and HMGB1 preclinical programs, are still in

development and remain subject to clinical testing and regulatory approval or clearance. In order to obtain regulatory approvals or clearances for the commercial sale of Critical Therapeutics product candidates, Critical Therapeutics and its collaborators will be required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of Critical Therapeutics product candidates. Critical Therapeutics may not be able to obtain authority from the FDA, institutional review boards or other regulatory agencies to commence or complete these clinical trials. If permitted, such clinical testing may not prove that Critical Therapeutics product candidates are safe and effective to the extent necessary to permit Critical Therapeutics to obtain marketing approvals or clearances from regulatory authorities. One or more of Critical Therapeutics product candidates may not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude submission and regulatory approval or clearance or limit commercial use if approved or cleared. Furthermore, Critical Therapeutics, one of its collaborators, institutional review boards or regulatory agencies may hold, suspend or terminate clinical trials at any time if it is believed that the subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons.

For example, in March 2006, Critical Therapeutics announced that it had discontinued a Phase II clinical trial of ethyl pyruvate, which Critical Therapeutics refers to as CTI-01, a small molecule product candidate that Critical Therapeutics had been developing for prevention of complications that can occur in patients after cardiopulmonary bypass, a procedure commonly performed during heart surgery. After reviewing the final data from the trial, Critical Therapeutics decided to discontinue further development of CTI-01. Critical Therapeutics subsequently terminated, effective in February 2007, the license agreements between Critical Therapeutics and the University of Pittsburgh and Xanthus Pharmaceuticals, Inc., formerly Phenome Sciences, Inc., or Xanthus Pharmaceuticals, related to patent rights related to CTI-01 controlled by University of Pittsburgh and Xanthus Pharmaceuticals.

Preclinical testing and clinical trials of new drug and biologic candidates are lengthy and expensive and the historical failure rate for such candidates is high. Critical Therapeutics may not be able to advance any more product candidates into clinical trials. Even if Critical Therapeutics does successfully enter into clinical trials, the results from preclinical testing of a product candidate may not predict the results that will be obtained in human clinical trials. In addition, positive results demonstrated in preclinical studies and clinical trials that Critical Therapeutics completes may not be indicative of results obtained in additional clinical trials. Clinical trials may take several years to complete, and failure can occur at any stage of testing.

Adverse or inconclusive clinical trial results concerning any of Critical Therapeutics product candidates could require Critical Therapeutics to conduct additional clinical trials, result in increased costs and significantly delay the submission for marketing approval or clearance for such product candidates with the FDA or other regulatory authorities or result in a submission or approval for a narrower indication. If clinical trials fail, Critical Therapeutics product candidates would not become commercially viable.

***If clinical trials for Critical Therapeutics product candidates are delayed, Critical Therapeutics would be unable to commercialize its product candidates on a timely basis, which would require Critical Therapeutics to incur additional costs and delay the receipt of any revenues from product sales.***

Critical Therapeutics cannot predict whether it will encounter problems with any of its completed, ongoing or planned clinical trials that will cause regulatory authorities, institutional review boards, one of its collaborators or Critical Therapeutics to delay or suspend those clinical trials, or delay the analysis of data from Critical Therapeutics ongoing clinical trials.

Any of the following could delay the completion of Critical Therapeutics ongoing and planned clinical trials:

ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of Critical Therapeutics clinical trials;

delays or the inability to obtain required approvals from institutional review boards or other governing entities at clinical sites selected for participation in Critical Therapeutics clinical trials;

delays in enrolling patients and volunteers into clinical trials;

lower than anticipated retention rates of patients and volunteers in clinical trials;

Table of Contents

the need to repeat clinical trials as a result of inconclusive or negative results or poorly executed testing;

insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct Critical Therapeutics clinical trials;

unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;

serious and unexpected drug-related side effects experienced by participants in ongoing or past clinical trials for the same or a different indication;

serious and unexpected drug-related side effects observed during ongoing or past preclinical studies; or

the placement of a clinical hold on a trial.

Critical Therapeutics ability to enroll patients in its clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the seasonality of the disease, the availability of effective treatments for the relevant disease, competing trials with other product candidates and the eligibility criteria for the clinical trial. Delays in patient enrollment can result in increased costs and longer development times. In addition, subjects may drop out of Critical Therapeutics clinical trials and thereby impair the validity or statistical significance of the trials. Delays in patient enrollment and the related increase in costs also could cause Critical Therapeutics to decide to discontinue a clinical trial prior to completion of the trial.

For example, in March 2008, Critical Therapeutics discontinued its Phase IV clinical trial for ZYFLO CR designed to generate data in the current patient treatment setting because of patient enrollment that was significantly slower than Critical Therapeutics had anticipated. Critical Therapeutics initiated the trial in July 2007 and had enrolled only approximately 25% of the patients prior to discontinuing the trial. Critical Therapeutics had planned to use data from this trial to support ZYFLO CR s market position, and Critical Therapeutics may have increased difficulty promoting ZYFLO CR to physicians without this data.

Critical Therapeutics expects to rely on academic institutions and contract research organizations to supervise or monitor some or all aspects of the clinical trials for the product candidates Critical Therapeutics advances into clinical testing. Accordingly, Critical Therapeutics has less control over the timing and other aspects of these clinical trials than if Critical Therapeutics conducted them entirely on its own.

As a result of these factors, Critical Therapeutics or third parties on whom Critical Therapeutics relies may not successfully begin or complete Critical Therapeutics clinical trials in the time periods Critical Therapeutics has forecasted, if at all. If the results of Critical Therapeutics ongoing or planned clinical trials for Critical Therapeutics product candidates are not available when Critical Therapeutics expects or if Critical Therapeutics encounters any delay in the analysis of data from Critical Therapeutics preclinical studies and clinical trials, Critical Therapeutics may be unable to submit its product candidates for regulatory approval or clearance or conduct additional clinical trials on the schedule Critical Therapeutics currently anticipates.

If clinical trials are delayed, the commercial viability of Critical Therapeutics product candidates may be reduced. If Critical Therapeutics incurs costs and delays in its programs, or if Critical Therapeutics does not successfully develop and commercialize its products, Critical Therapeutics future operating and financial results will be materially affected.

***Even if Critical Therapeutics obtains regulatory approvals or clearances, Critical Therapeutics products and product candidates will be subject to ongoing regulatory requirements and review. If Critical Therapeutics fails to comply with continuing U.S. and applicable foreign regulations, Critical Therapeutics could lose permission to manufacture, distribute and sell its products and, if approved, its product candidates.***

Critical Therapeutics products and product candidates are subject to continuing regulatory review after approval, including the review of spontaneous adverse drug experiences and clinical results from any post-market testing required as a condition of approval that are reported after Critical Therapeutics product candidates become commercially available. The manufacturer and the manufacturing facilities Critical Therapeutics uses to make ZYFLO CR, ZYFLO CR tablet cores, ZYFLO and zileuton API and any of its

Table of Contents

product candidates will also be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer or facility, including withdrawal of the product from the market. Critical Therapeutics product promotion and advertising will also be subject to regulatory requirements and continuing FDA review.

As part of the approval of the NDA for ZYFLO CR in May 2007, the FDA required Critical Therapeutics to conduct a pediatric clinical trial of ZYFLO CR as a post-approval commitment and report the results to the FDA by June 2010. If Critical Therapeutics does not successfully begin and complete this clinical trial in the time required by the FDA, Critical Therapeutics ability to market and sell ZYFLO CR may be hindered, and Critical Therapeutics business may be harmed as a result.

Numerous proposals have been made in recent months and years to impose new requirements on drug approvals, expand post-approval requirements, and restrict sales and promotional activities. For example, an NDA requires that an applicant submit risk evaluation and minimization plans to monitor and address potential safety issues for products upon approval, and federal legislation has been proposed that would require all new drug applicants to submit risk evaluation and minimization plans to monitor and address potential safety issues for products upon approval, grant the FDA the authority to impose risk management measures for marketed products and to mandate labeling changes in certain circumstances, and establish new requirements for disclosing the results of clinical trials. Additional measures have also been proposed to address perceived shortcomings in the FDA s handling of drug safety issues, and to limit pharmaceutical company sales and promotional practices that some see as excessive or improper. If these or other legal or regulatory changes are enacted, it may become more difficult or burdensome for Critical Therapeutics to obtain extended or new product approvals, and Critical Therapeutics current approvals may be restricted or subject to onerous post-approval requirements. Such changes may increase Critical Therapeutics costs and adversely affect Critical Therapeutics operations. The ability of Critical Therapeutics or its partners to commercialize approved products successfully may be hindered, and Critical Therapeutics business may be harmed as a result.

***If Critical Therapeutics or its third-party manufacturers or service providers fail to comply with applicable laws and regulations, Critical Therapeutics or they could be subject to enforcement actions, which could adversely affect Critical Therapeutics ability to market and sell Critical Therapeutics product candidates and may harm Critical Therapeutics reputation.***

If Critical Therapeutics or its third-party manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, Critical Therapeutics could be subject to enforcement actions, which could adversely affect Critical Therapeutics ability to develop, market and sell Critical Therapeutics product candidates successfully and may harm Critical Therapeutics reputation and hinder market acceptance of Critical Therapeutics product candidates. These enforcement actions include:

- product seizures;
- voluntary or mandatory recalls;
- suspension of review or refusal to approve pending applications;
- voluntary or mandatory patient or physician notification;
- withdrawal of product approvals;
- restrictions on, or prohibitions against, marketing Critical Therapeutics product candidates;

restrictions on applying for or obtaining government bids;

fines;

restrictions on importation of Critical Therapeutics product candidates;

injunctions; and

civil and criminal penalties.

Table of Contents

***If the market is not receptive to Critical Therapeutics product candidates, Critical Therapeutics will be unable to generate revenues from sales of these products.***

The probability of commercial success of each of Critical Therapeutics product candidates is subject to significant uncertainty. Factors that Critical Therapeutics believes will materially affect market acceptance of Critical Therapeutics product candidates under development include:

- the timing of Critical Therapeutics receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;
- the safety, efficacy and ease of administration;
- the therapeutic benefit or other improvement over existing comparable products;
- pricing and cost effectiveness;
- the ability to be produced in commercial quantities at acceptable costs;
- the availability of reimbursement from third-party payors such as state and federal governments, under programs such as Medicare and Medicaid, and private insurance plans and MCOs; and
- the extent and success of Critical Therapeutics sales and marketing efforts.

The failure of Critical Therapeutics product candidates to achieve market acceptance would prevent Critical Therapeutics from ever generating meaningful revenues from sales of these product candidates.

**Risks Relating to Critical Therapeutics Common Stock**

***Critical Therapeutics stock price is subject to fluctuation, which may cause an investment in Critical Therapeutics stock to suffer a decline in value.***

The market price of Critical Therapeutics common stock may fluctuate significantly in response to factors that are beyond Critical Therapeutics control. The stock market in general has recently experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been extremely volatile and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of Critical Therapeutics common stock, which could cause a decline in the value of Critical Therapeutics common stock. For example, between September 1, 2007 and , 2008, the last practicable date before the printing of this proxy statement/prospectus, the trading price of Critical Therapeutics common stock as reported on NASDAQ ranged from a high of $ per share to a low of $ per share. On April 30, 2008, the last day prior to the public announcement of the proposed merger, the closing price per share of Critical Therapeutics common stock as reported on The NASDAQ Global Market was $0.62. On , 2008, the last practicable date before the printing of this proxy statement/prospectus, the closing price per share of Critical Therapeutics common stock as reported on The NASDAQ Capital Market was $ , which represents a % decrease from the closing price on April 30, 2008.

***If Critical Therapeutics fails to continue to meet all applicable continued listing requirements of The NASDAQ Capital Market and NASDAQ determines to delist Critical Therapeutics common stock, the market liquidity and market price of Critical Therapeutics common stock could decline.***

Critical Therapeutics common stock is currently listed on The NASDAQ Capital Market. In order to maintain that listing, Critical Therapeutics must satisfy minimum financial and other listing requirements.

On April 21, 2008, Critical Therapeutics received notification from the NASDAQ Listings Qualification Department that for the prior 30 consecutive business days the bid price of its common stock on The NASDAQ Global Market had closed below the minimum $1.00 per share required for continued inclusion under NASDAQ Marketplace Rule 4450(a)(5). On May 16, 2008, Critical Therapeutics received notification from the NASDAQ Listings Qualification Department that its stockholders equity of $7,126,000, as reported in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 that it filed with the SEC, does not comply with the minimum stockholders equity requirement of $10,000,000 for continued listing on The NASDAQ Global Market pursuant to NASDAQ Marketplace Rule 4450(a)(3).

Table of Contents

On June 13, 2008, NASDAQ approved the transfer of the listing of Critical Therapeutics common stock from The NASDAQ Global Market to The NASDAQ Capital Market effective at the opening of business on June 17, 2008. A condition to approval of the transfer of the listing was Critical Therapeutics satisfaction of The NASDAQ Capital Market s continued listing requirements, other than the $1.00 per share minimum bid price requirement. Separately, if Critical Therapeutics meets all of The NASDAQ Capital Market s initial listing requirements, other than the minimum bid price requirement, on October 20, 2008, which is the date that is 180 days following the date Critical Therapeutics received notification from NASDAQ that it failed to comply with the minimum bid price requirement, Critical Therapeutics will have the remainder of an additional 180 calendar day grace period while listed on The NASDAQ Capital Market to regain compliance with NASDAQ s minimum bid price requirement. There can be no assurance that on October 20, 2008 Critical Therapeutics will comply with The NASDAQ Capital Market s initial listing requirements, including The NASDAQ Capital Market s minimum stockholders equity requirement.

On August 13, 2008, Critical Therapeutics received notification from the NASDAQ Listing Qualification Department that, based on its stockholders equity of $1.2 million, as reported in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, and a market value of its common stock as of August 12, 2008 of $13.0 million, Critical Therapeutics does not comply with NASDAQ Marketplace Rule 4310(c)(3), which requires it to have, for continued listing on The NASDAQ Capital Market, a minimum of $2.5 million in stockholders equity or market value of listed securities of $35.0 million or $500,000 of net income from continuing operations for the most recently completed fiscal year or two of the three most recently completed fiscal years. As a result, the Listing Qualifications Staff is reviewing Critical Therapeutics eligibility for continued listing on The NASDAQ Capital Market. To facilitate the review, Critical Therapeutics provided to the Listing Qualifications Staff on September 3, 2008 a definitive plan, based on completing the proposed merger with Cornerstone, to achieve and sustain compliance with all NASDAQ Capital Market listing requirements. If after the conclusion of its review process the Listing Qualifications Staff determines that Critical Therapeutics plan does not adequately address the deficiencies noted, the Staff will provide written notice to Critical Therapeutics that its common stock will be delisted from The NASDAQ Capital Market. In such event, Critical Therapeutics may appeal the Staff s decision to a NASDAQ Listing Qualifications Panel.

If Critical Therapeutics fails to continue to meet all applicable listing requirements of The NASDAQ Capital Market and NASDAQ determines to delist its common stock, an active trading market for Critical Therapeutics common stock may not be sustained and the market price of Critical Therapeutics common stock could decline. If an active trading market for Critical Therapeutics common stock is not sustained, it will be difficult for Critical Therapeutics stockholders to sell shares of Critical Therapeutics common stock without further depressing the market price of Critical Therapeutics common stock or at all. A delisting of Critical Therapeutics common stock also could make it more difficult for Critical Therapeutics to obtain financing for the continuation of Critical Therapeutics operations and could result in the loss of confidence by investors, suppliers and employees.

Immediately prior to the effective time of the merger, Critical Therapeutics has agreed to effect a reverse stock split of Critical Therapeutics common stock such that outstanding shares of Critical Therapeutics common stock will be reclassified and combined into a lesser number of shares such that one share of Critical Therapeutics common stock will be issued for a specified number of shares, to be mutually agreed upon by Critical Therapeutics and Cornerstone, which shall be greater than one and equal to or less than 50, of outstanding Critical Therapeutics common stock, with the exact number within the range to be determined by Critical Therapeutics board of directors prior to the effective time of the amendment to Critical Therapeutics certificate of incorporation effecting the reverse stock split and publicly announced by Critical Therapeutics. The reverse stock split is necessary so that as of the effective time of the merger Critical Therapeutics will satisfy the minimum bid price requirement pursuant to NASDAQ s initial listing standards.

Table of Contents

***If Critical Therapeutics quarterly results of operations fluctuate, this fluctuation may subject Critical Therapeutics stock price to volatility, which may cause an investment in Critical Therapeutics stock to suffer a decline in value.***

Critical Therapeutics quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. A number of factors, many of which are not within Critical Therapeutics control, could subject Critical Therapeutics operating results and stock price to volatility, including:

- Critical Therapeutics proposed merger with Cornerstone and related developments, including the timing thereof;
- the amount and timing of sales of ZYFLO CR and ZYFLO;
- the timing of operating expenses, including selling and marketing expenses and the costs of maintaining a direct sales force;
- the availability and timely delivery of a sufficient supply of ZYFLO CR and ZYFLO;
- the amount of rebates, discounts and chargebacks to wholesalers, Medicaid and MCOs related to ZYFLO CR and ZYFLO;
- the amount and timing of product returns for ZYFLO CR and ZYFLO;
- achievement of, or the failure to achieve, milestones under Critical Therapeutics development agreement with MedImmune, Critical Therapeutics license agreements with Beckman Coulter and SetPoint and, to the extent applicable, other licensing and collaboration agreement;
- the results of ongoing and planned clinical trials of Critical Therapeutics product candidates;
- production problems occurring at Critical Therapeutics third-party manufacturers;
- the results of regulatory reviews relating to the development or approval of Critical Therapeutics product candidates; and
- general and industry-specific economic conditions that may affect Critical Therapeutics research and development expenditures.

Due to the possibility of significant fluctuations, Critical Therapeutics does not believe that quarterly comparisons of Critical Therapeutics operating results will necessarily be indicative of Critical Therapeutics future operating performance. If Critical Therapeutics quarterly operating results fail to meet the expectations of stock market analysts and investors, the price of Critical Therapeutics common stock may decline.

***If significant business or product announcements by Critical Therapeutics or Critical Therapeutics competitors cause fluctuations in Critical Therapeutics stock price, an investment in Critical Therapeutics stock may suffer a decline in value.***

The market price of Critical Therapeutics common stock may be subject to substantial volatility as a result of announcements by Critical Therapeutics or other companies in Critical Therapeutics industry, including Critical Therapeutics collaborators. Announcements that may subject the price of Critical Therapeutics common stock to

substantial volatility include announcements regarding:

- developments with respect to Critical Therapeutics proposed merger with Cornerstone;
- Critical Therapeutics operating results, including the amount and timing of sales of ZYFLO CR and ZYFLO;
- the availability and timely delivery of a sufficient supply of ZYFLO CR and ZYFLO;
- Critical Therapeutics licensing and collaboration agreements and the products or product candidates that are the subject of those agreements;
- the results of discovery, preclinical studies and clinical trials by Critical Therapeutics or Critical Therapeutics competitors;
- the acquisition of technologies, product candidates or products by Critical Therapeutics or Critical Therapeutics competitors;

Table of Contents

the development of new technologies, product candidates or products by Critical Therapeutics or Critical Therapeutics competitors;

regulatory actions with respect to Critical Therapeutics product candidates or products or those of Critical Therapeutics competitors; and

significant acquisitions, strategic partnerships, joint ventures or capital commitments by Critical Therapeutics or Critical Therapeutics competitors.

**Risks Relating to Termination of the Merger Agreement or Other Failure to Consummate the Merger**

***If the proposed merger with Cornerstone is not consummated, Critical Therapeutics business could suffer materially and Critical Therapeutics stock price could decline.***

The consummation of the proposed merger with Cornerstone is subject to a number of closing conditions, including the approval by Critical Therapeutics stockholders, approval by NASDAQ of Critical Therapeutics application for re-listing of Critical Therapeutics common stock in connection with the merger, the continued availability of Critical Therapeutics products and other customary closing conditions. Critical Therapeutics is targeting a closing of the transaction in the fourth quarter of 2008.

If the proposed merger is not consummated, Critical Therapeutics may be subject to the following risks:

Critical Therapeutics has incurred and expects to continue to incur significant expenses related to the proposed merger with Cornerstone. As of August 31, 2008, Critical Therapeutics had approximately $1.8 million of fees and expenses billed and accrued in connection with the proposed merger for legal, financial advisory, accounting and other services. These fees and expenses are payable by Critical Therapeutics even if the merger is not consummated.

If the merger agreement is terminated, Critical Therapeutics will have a limited ability to continue its current operations without obtaining additional financing to fund its operations.

Critical Therapeutics could be obligated to pay Cornerstone a $1.0 million termination fee and to reimburse Cornerstone for up to $150,000 in expenses in connection with the termination of the merger agreement, depending on the reason for the termination. Critical Therapeutics would not be obligated to pay Cornerstone the $1.0 million termination fee if Critical Therapeutics stockholders fail to approve the proposals presented at the special meeting unless at or prior to the time of such failure an acquisition proposal relating to Critical Therapeutics was announced and was not abandoned or withdrawn.

Critical Therapeutics customers, prospective customers, collaborators and other business partners and investors in general may view the failure to consummate the merger as a poor reflection on its business or prospects.

The market price of Critical Therapeutics common stock may decline further to the extent that the current market price reflects a market assumption that the proposed merger will be completed.

In addition, if the merger agreement is terminated and Critical Therapeutics board of directors determines to seek another business combination, it may not be able to find a third party willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the merger. In such circumstances, Critical Therapeutics board of directors may elect to, among other things, divest all or a portion of Critical Therapeutics

business, or take the steps necessary to liquidate all of Critical Therapeutics business and assets, and in either such case, the consideration that Critical Therapeutics receives may be less attractive than the consideration to be received by Critical Therapeutics pursuant to the merger agreement.

***If the Delaware Court of Chancery enjoins Critical Therapeutics from proceeding with the merger, Critical Therapeutics will have a limited ability to continue its current operations if a third party is unwilling to provide equivalent or more attractive consideration than proposed in connection with the proposed merger with Cornerstone.***

On September 17, 2008, a purported shareholder class action lawsuit was filed by a single plaintiff against Critical Therapeutics and each of its directors in the Court of Chancery of The State of Delaware. The complaint alleges, among other things, that the defendants breached fiduciary duties of loyalty and good faith,

Table of Contents

including a fiduciary duty of candor, by failing to provide Critical Therapeutics stockholders with a proxy statement/prospectus adequate to enable them to cast an informed vote on the proposed merger, and by possibly failing to maximize stockholder value by entering into an agreement that effectively discourages competing offers. The complaint seeks, among other things, an order (i) enjoining the defendants from proceeding with or implementing the proposed merger on the terms and under the circumstances as they presently exist, (ii) invalidating the provisions of the proposed merger that purportedly improperly limit the effective exercise of the defendants continuing fiduciary duties; (iii) ordering defendants to explore alternatives and to negotiate in good faith with all *bona fide* interested parties; (iv) in the event the proposed merger is consummated, rescinding it and setting it aside or awarding rescissory damages; (v) awarding compensatory damages against defendants, jointly and severally; and (vi) awarding the plaintiff and the purported class their costs and fees.

If the Court of Chancery enjoins Critical Therapeutics from proceeding with the merger and the merger is not consummated, Critical Therapeutics may be subject to each of the risks described in the immediately preceding risk factor. In particular, if the proposed merger with Cornerstone is not consummated, Critical Therapeutics will have a limited ability to continue its current operations without obtaining additional financing. If Critical Therapeutics board of directors determines to seek another business combination, it may not be able to find a third party willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the merger. In addition, defending against the lawsuit will be costly and time consuming for Critical Therapeutics and may distract Critical Therapeutics management from day to day operations. If the lawsuit is successful, Critical Therapeutics could be required to pay monetary damages and the plaintiffs costs and fees.

## Risks Related to Cornerstone

### Risks Relating to Commercialization and Acquisitions

***Cornerstone has derived substantially all of its revenues from sales of the ALLERX Dose Pack products, SPECTRACEF and BALACET 325.***

Cornerstone has derived and expects for the foreseeable future to continue to derive substantially all of its revenues from sales of AlleRx®, or ALLERX, Dose Pack products, Spectracef® (cefditoren pivoxil), or SPECTRACEF, and Balacet® 325 (propoxyphene napsylate and acetaminophen), or BALACET 325. If commercial, regulatory or other developments adversely affect Cornerstone s ability to market these products or if demand for these products is reduced, Cornerstone s business, financial condition and operating results could be materially harmed. Until one or more of Cornerstone s product candidates receive FDA approval and is successfully commercialized, the success of Cornerstone s business and its operating results will depend substantially on the demand for and continued marketability of the ALLERX Dose Pack products, SPECTRACEF and BALACET 325.

***The commercial success of Cornerstone s currently marketed products and any additional products that it successfully develops depends and will depend on the degree of market acceptance by physicians, patients, health care payors and others in the medical community.***

Any products that Cornerstone brings to the market may not gain market acceptance by physicians, patients, health care payors and others in the medical community. If its products do not achieve an adequate level of acceptance, Cornerstone may not generate significant product revenue and may not become profitable. The degree of market acceptance of Cornerstone s products, including its product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of the products side effects;

the efficacy and potential advantages of the products over alternative treatments;

the ability to offer the products for sale at competitive prices, including in relation to any generic or re-imported products or competing treatments;

the relative convenience and ease of administration of the products;

Table of Contents

the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

the perception by physicians and other members of the health care community of the safety and efficacy of the products and competing products;

the availability and level of third-party reimbursement for sales of the products;

the continued availability of adequate supplies of the products to meet demand;

the strength of marketing and distribution support;

any unfavorable publicity concerning Cornerstone, its products or the markets for these products, such as information concerning product contamination or other safety issues in the markets for Cornerstone s products, whether or not directly involving Cornerstone s products;

regulatory developments related to Cornerstone s marketing and promotional practices or the manufacture or continued use of its products; and

changes in intellectual property protection available for the products or competing treatments.

For example, SPECTRACEF and the SPECTRACEF line extensions are indicated for the treatment of respiratory infections. Products used to treat respiratory infections are, from time to time, subject to negative publicity, including with respect to antibiotic resistance and overuse.

***Concerns regarding the potential toxicity and addictiveness of propoxyphene and the known liver toxicity of acetaminophen may limit market acceptance of BALACET 325, APAP 325 and APAP 500 or cause the FDA to remove these products from the market.***

Periodically, there is negative publicity related to the potential toxicity and addictiveness of propoxyphene. Propoxyphene is one of two active pharmaceutical ingredients, together with acetaminophen, in BALACET 325, Propoxyphene-APAP 100-325, or APAP 325, and Propoxyphene-APAP 100-500, or APAP 500. For example, the consumer advocacy organization Public Citizen filed suit in June 2008 against the FDA based on the FDA s failure to act on Public Citizen s February 2006 citizen petition that had requested that the FDA immediately begin the phased removal of all drugs containing propoxyphene from the marketplace based on propoxyphene s toxicity relative to its efficacy and its tendency to induce psychological and physical dependence. Although Cornerstone is not a party to this proceeding, if the FDA granted the citizen petition and began the phased removal of propoxyphene from the market, product sales of BALACET 325, APAP 325 and APAP 500 would be eliminated and Cornerstone would likely be forced to terminate its co-promotion agreement with Atley Pharmaceuticals, Inc., or Atley Pharmaceuticals.

In December 2006, the FDA recognized concerns about the known liver toxicity of over-the-counter pain relievers, including acetaminophen, which is found in BALACET 325, APAP 325 and APAP 500. The FDA could act on these concerns by changing its policies with respect to acetaminophen and opioid combination products. Any such future policy change could adversely affect Cornerstone s ability to market BALACET 325, APAP 325 and APAP 500.

***Cornerstone s strategy of obtaining, through acquisitions and in-licenses, rights to products and product candidates for its development pipeline and to proprietary drug delivery and formulation technologies for its life cycle management of current products may not be successful.***

Part of Cornerstone s business strategy is to acquire rights to FDA-approved products, pharmaceutical product candidates in the late stages of development and proprietary drug delivery and formulation technologies. Because Cornerstone does not have discovery and research capabilities, the growth of its business will depend in significant part on its ability to acquire or in-license additional products, product candidates or proprietary drug delivery and formulation technologies that it believes have significant commercial potential and are consistent with its commercial objectives. However, it may be unable to license or acquire suitable products, product candidates or technologies from third parties for a number of reasons. Cornerstone has limited resources to acquire third-party products, product candidates and technologies and integrate them into its current infrastructure. The licensing and acquisition of pharmaceutical products, product candidates and related technologies is a competitive area, and a number of more established companies are also pursuing strategies to

Table of Contents

license or acquire products, product candidates and drug delivery and formulation technologies, which may mean fewer suitable acquisition opportunities for Cornerstone, as well as higher acquisition prices. Many of Cornerstone s competitors have a competitive advantage over Cornerstone due to their size, cash resources and greater clinical development and commercialization capabilities. Other factors that may prevent Cornerstone from licensing or otherwise acquiring suitable products, product candidates or technologies include:

- Cornerstone may be unable to license or acquire the relevant products, product candidates or technologies on terms that would allow it to make an appropriate return on investment;
- companies that perceive Cornerstone as a competitor may be unwilling to assign or license their product rights or technologies to it;
- Cornerstone may be unable to identify suitable products, product candidates or technologies within its areas of expertise; and
- Cornerstone may have inadequate cash resources or may be unable to obtain financing to acquire rights to suitable products, product candidates or technologies from third parties.

If Cornerstone is unable to successfully identify and acquire rights to products, product candidates and proprietary drug delivery and formulation technologies and successfully integrate them into its operations, it may not be able to increase its revenues in future periods, which could result in significant harm to its financial condition, results of operations and prospects. Cornerstone is not currently actively engaged in any discussions with any person regarding the acquisition of rights to products, product candidates or drug delivery and formulation technologies that have advanced to a binding term sheet or similar stage.

***If Cornerstone is unable to expand its sales force and marketing capabilities, the commercial opportunity for its products and product candidates may be diminished.***

Cornerstone has built a commercial organization, consisting of its sales department, including its sales force, sales management, sales logistics and sales administration, and its marketing department, that currently focuses on marketing and promoting Cornerstone s SPECTRACEF and the ALLERX Dose Pack products. As of September 15, 2008, this organization included a respiratory-focused sales team made up of 49 sales representatives that calls on primary care physicians, allergists, otolaryngologists, pulmonologists, infectious disease specialists, physician assistants, nurse practitioners and pharmacists. However, to date Cornerstone has not commercialized a newly approved product. Cornerstone plans to recruit additional sales professionals to expand its specialty sales force as it prepares for the commercial launch of SPECTRACEF Suspension, subject to FDA approval. If Cornerstone successfully completes development and receives FDA approval of its methscopolamine and antihistamine combination product candidate, it expects to further expand its specialty sales force to promote this additional product. In addition, Cornerstone currently is in the process of expanding its marketing team to prepare for the potential commercial launch of these product candidates.

Cornerstone previously conducted reductions in force in each of January 2006 and April 2008, which may negatively affect its ability to attract and retain additional sales and marketing personnel. Cornerstone may not be able to attract, hire, train and retain qualified sales and marketing personnel to augment its existing capabilities in the manner or on the timeframe that it is currently planning. If Cornerstone is not successful in its efforts to expand its sales force and marketing capabilities, its ability to independently market and promote any product candidates that it successfully brings to market will be impaired. In such an event, Cornerstone would likely need to establish a collaboration, co-promotion, distribution or other similar arrangement to market and sell the product candidate. However, Cornerstone might not be able to enter into such an arrangement on favorable terms, if at all.

Expanding Cornerstone s sales force and marketing group will be expensive and time consuming and could delay a product launch. Companies such as Cornerstone typically expand their sales force and marketing capabilities for a product prior to it being approved by the FDA so that the drug can be commercialized upon approval. If the commercial launch of a product candidate for which Cornerstone recruits a sales force and establishes marketing capabilities is delayed as a result of FDA requirements or other reasons, Cornerstone would incur the expense of the additional sales and marketing personnel prior to being able to realize any revenue from the sales of the product candidate. This may be costly, and Cornerstone s investment would be lost if it cannot retain its sales and marketing personnel. Even if Cornerstone is able to effectively expand its

Table of Contents

sales force and marketing capabilities, its sales force and marketing teams may not be successful in commercializing its products.

***Cornerstone faces competition, which may result in others discovering, developing or commercializing products before or more successfully than Cornerstone.***

The development and commercialization of drugs is highly competitive. Cornerstone faces competition with respect to its currently marketed products, its current product candidates and any products it may seek to develop or commercialize in the future. Cornerstone s competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other private and public research organizations that seek patent protection and establish collaborative arrangements for development, manufacturing and commercialization. Cornerstone faces significant competition for its currently marketed products. Some of its currently marketed products do not have patent protection and in most cases face generic competition. All of these products face significant price competition from a range of branded and generic products for the same therapeutic indications.

Given that Cornerstone s product development approach is to develop new formulations of existing drugs, some or all of its product candidates, if approved, may face competition from generic and branded formulations of these existing drugs, as well as significant price competition. Cornerstone s product candidates, if approved, will compete with other branded and generic drugs approved for the same therapeutic indications, approved drugs used off label for such indications and novel drugs in clinical development. For example, Cornerstone s methscopolamine/antihistamine product candidate, which is a modified formulation of an existing product, may not demonstrate sufficient additional clinical benefits to physicians to justify a higher price compared to generic equivalents within the same therapeutic class. Cornerstone s commercial opportunity could be reduced or eliminated if its competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are more convenient or are less expensive than any products that Cornerstone may develop.

Cornerstone s patents will not protect its products if competitors devise ways of making products that compete with Cornerstone s products without legally infringing its patents. The FDCA and FDA regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug in order to facilitate the approval of abbreviated NDAs, or ANDAs, for generic substitutes. These same types of incentives encourage manufacturers to submit NDAs that rely, in part, on literature and clinical data not prepared for or by such manufacturers. Manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same API, dosage form, strength, route of administration and conditions of use or labeling as Cornerstone s product and that the generic product is absorbed in the body at the same rate and to the same extent as Cornerstone s product, a comparison known as bioequivalence. Such products would be significantly less costly than Cornerstone s products to bring to market and could lead to the existence of multiple lower-priced competitive products, which would substantially limit Cornerstone s ability to obtain a return on the investments it has made in those products.

Cornerstone s competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than Cornerstone may obtain approval for its product candidates. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active pharmaceutical ingredients but is approved in a new dosage strength, dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor. During such three-year exclusivity period, the FDA cannot grant effective approval of an ANDA or a Section 505(b)(2) NDA to commercially distribute a version of the drug based on that listed drug. Federal law also provides a five-year period of exclusivity following approval of a drug containing no previously approved active pharmaceutical ingredients. If a Cornerstone competitor obtains approval of a product that uses the same API for the same indication as a Cornerstone product candidate, Cornerstone would not be able to receive FDA approval of its product candidate until the

applicable exclusivity period had expired.

**Table of Contents**

Cornerstone s products compete, and its product candidates, if approved, will compete, principally with the following:

*SPECTRACEF, SPECTRACEF 400 mg and SPECTRACEF Once Daily* second and third generation cephalosporins, such as Shionogi USA, Inc. s Cedax® (ceftibuten), Lupin Pharmaceuticals, Inc. s, or Lupin Pharmaceuticals, Suprax® (cefixime) and generic formulations of Abbott Laboratories, Inc. s Omnicef® (cefdinir), Pharmacia and Upjohn Company, Inc. s Vantin® (cefpodoxime), GlaxoSmithKline plc s Ceftin® (cefuroxime) and Bristol-Myers Squibb Company s Cefzil® (cefprozil); macrolides, such as generic formulations of Pfizer Inc. s Zithromax® (azithromycin) and Abbott Laboratories, Inc. s Biaxin® (clarithromycin); and quinolones, such as Ortho-McNeil-Janssen Pharmaceuticals, Inc. s Levaquin® (levofloxacin) and generic formulations of Bayer AG s Cipro® (ciprofloxacin).

*SPECTRACEF Suspension* Suprax and generic formulations of Omnicef and Ceftin.

*ALLERX and RespiVent™, or RESPIVENT, Dose Pack Products* prescription products, including first generation antihistamine and antihistamine combination products, such as Capellon Pharmaceuticals, Ltd. s Rescon-MX® (chlorpheniramine, methscopolamine and phenylephrine), Poly Pharmaceuticals, Inc. s Poly Hist Forte® (chlorpheniramine, phenylephrine and pyrilamine) and Laser Pharmaceuticals, LLC s Dallergy® (phenylephrine, chlorpheniramine and methscopolamine); and over-the-counter products, such as McNeil PPC, Inc. s Zyrtec® (cetirizine), Schering-Plough Corporation s Claritin® (loratadine) and Chlor-Trimeton® (chlorpheniramine) and McNeil PPC, Inc. s Benadryl® (diphenhydramine).

*BALACET 325, APAP 325 and APAP 500* generic formulations of propoxyphene and acetaminophen, the active pharmaceutical ingredients in BALACET 325, APAP 325 and APAP 500, and many other drugs on the market or in development for the treatment of mild to moderate pain.

*Hyomax™, or HYOMAX, Products* belladonna and derivative antispasmodics, such as the generic formulations of Alaven Pharmaceutical LLC s Levsin® (hyoscyamine sulfate) and Levbid® (hyoscyamine sulfate); synthetic gastrointestinal antispasmodics, such as the generic formulations of Axcan Pharma Inc. s Bentyl® (dicyclomine) and Kenwood Therapeutics Pamine® (methscopolamine bromide).

*Methscopolamine and Antihistamine Combination Product Candidate* second generation antihistamines, such as Sanofi-Aventis U.S. LLC s Allegra® (fexofenadine); third generation antihistamines, such as UCB, Inc. and Sanofi-Aventis U.S. LLC s Xyzal® (levocetirizine) and Schering-Plough Corporation s Clarinex® (desloratadine); first generation antihistamine combination products, which are mostly generic; and over-the-counter antihistamines, such as Claritin, Zyrtec, Benadryl and Chlor-Trimeton.

*Hydrocodone Cough Suppressant Product Candidates* Endo Pharmaceuticals Hycodan® (hydrocodone) and King Pharmaceuticals Tussigon® (hydrocodone and homatropine), Mallinckrodt Medical Inc. s TussiCaps® (hydrocodone polistirex and chlorpheniramine polistirex) and UCB Pharma s Tussionex® (hydrocodone polistirex and chlorpheniramine polistirex); over-the-counter cough suppressants, such as Reckitt Benckiser s Delsym® (dextromethorphan polistirex), Wyeth s Robitussin-DM® (dextromethorphan and guaifenesin) and Procter & Gamble Company s Vicks Formula 44® Cough Relief (dextromethorphan, phenylephrine and chlorpheniramine); and prescription cough suppressants, such as Sciele Pharma, Inc. s Rondec® DM Syrup (chlorpheniramine, phenylephrine and dextromethorphan) and Meda Pharmaceuticals Inc. s Tussi-12D® (carbetapentane, pyrilamine and phenylephrine).

Many of Cornerstone s competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than it does. These competitors also compete with Cornerstone in recruiting and

retaining qualified scientific and management personnel, establishing clinical trial sites, registering patients for clinical trials and acquiring technologies complementary to, or necessary for, its programs or advantageous to its business. In many cases, products that compete with Cornerstone s currently marketed products and product candidates have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Table of Contents

***As its competitors introduce their own generic equivalents of Cornerstone s generic products, Cornerstone s net revenues from such products are expected to decline.***

Product sales of generic pharmaceutical products often follow a particular pattern over time based on regulatory and competitive factors. The first company to introduce a generic equivalent of a branded product is often able to capture a substantial share of the market. However, as other companies introduce competing generic products, the first entrant s market share, and the price of its generic product, will typically decline. The extent of the decline generally depends on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors. Cornerstone s inability to introduce additional generic products or its withdrawal of its existing generic products from the market due to increased competition would have a material adverse effect on its financial condition and results of operations.

For example, in the generic drug industry, when a company is the first to introduce a generic drug, the pricing of the generic drug is typically set based on the published price of the equivalent brand product. Other generic manufacturers may enter the market and, as a result, the price of the drug may decline significantly. In such event, Cornerstone may in its discretion provide its customers a credit with respect to the customers remaining inventory for the difference between Cornerstone s new price and the price at which Cornerstone originally sold the product to its customers. There are circumstances under which Cornerstone may, as a matter of business strategy, not provide price adjustments to certain customers and, consequently, may lose future sales to competitors.

***If Cornerstone fails to successfully manage its acquisitions, its ability to develop its product candidates and expand its product pipeline may be harmed.***

Cornerstone s failure to adequately address the financial, operational or legal risks of its acquisitions or in-license arrangements could harm its business. These risks include:

- the overuse of cash resources;
- higher than anticipated acquisition costs and expenses;
- potentially dilutive issuances of equity securities;
- the incurrence of debt and contingent liabilities, impairment losses and/or restructuring charges;
- the assumption of or exposure to unknown liabilities;
- the development and integration of new products that could disrupt Cornerstone s business and occupy its management s time and attention;
- the inability to preserve key suppliers or distributors of any acquired products; and
- the acquisition of products that could substantially increase its amortization expenses.

If Cornerstone is unable to successfully manage its acquisitions, its ability to develop new products and continue to expand its product pipeline may be limited, and it could suffer significant harm to its financial condition, results of operations and prospects.

***Cornerstone may experience significant inventory losses related to at risk generic product launches, which could have a material adverse effect on Cornerstone s business, financial position and results of operations.***

There are situations in which Cornerstone may make business and legal judgments to market and sell generic products that are subject to claims of alleged patent infringement prior to final resolution of those claims by the courts, based upon its belief that such patents are invalid, unenforceable or would not be infringed. This practice is referred to in the pharmaceutical industry as an at risk launch. The risk involved in an at risk launch can be substantial because, if the patent holder ultimately prevails, the remedies available to the holder may include, among other things, damages measured by the profits lost by the holder, which can be significantly higher than the actual profits Cornerstone made from selling the generic version of the product. Cornerstone would also be at risk for the value of the inventory that it is unable to sell.

Table of Contents

***A failure to maintain optimal inventory levels could harm Cornerstone s reputation and subject it to financial losses.***

Cornerstone is subject to minimum purchase obligations under its supply agreement with Meiji Seika Kaisha, Ltd., or Meiji, for the purchase of SPECTRACEF 200 mg and SPECTRACEF 400 mg. Under the agreement, the annual targeted gross sales of SPECTRACEF are $15.0 million for the first year beginning with the commercial launch of SPECTRACEF 200 mg or SPECTRACEF 400 mg manufactured by Meiji, whichever is earlier, $20.0 million for year two, $25.0 million for year three, $30.0 million for year four and $35.0 million for year five. If Cornerstone does not meet its minimum purchase requirement in a given year, Cornerstone must pay Meiji an amount equal to 50% of the shortfall in that year. If SPECTRACEF does not achieve the level of sales Cornerstone anticipates, Cornerstone may not be able to use all of the cefditoren pivoxil it is required to purchase. Cornerstone is using its current inventory of cefditoren pivoxil for formulation, development and manufacture of the currently marketed SPECTRACEF product as well as the SPECTRACEF line extensions.

Cornerstone is subject to minimum purchase obligations under its manufacturing agreement with Bayer Healthcare, LLC, or Bayer, for the purchase of bulk tablets for the ALLERX product line. Under the agreement, Cornerstone has a minimum annual purchase requirement of 27.0 million tablets per year for 2008 and 2009. If there are changes to the market that negatively impact the demand for ALLERX, Cornerstone would be required to pay Bayer a variable amount up to $135,000 based on the extent to which Cornerstone did not fulfill it minimum purchase obligations.

Because accurate product planning is necessary to ensure that Cornerstone maintains optimal inventory levels, significant differences between Cornerstone s current estimates and judgments and future estimated demand for its products and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. If Cornerstone is required to recognize charges for excess inventories, such charges could have a material adverse effect on its financial condition and results of operations. Due to significant differences between Cornerstone s sales forecasts and the actual demand for SPECTRACEF, Cornerstone currently has more SPECTRACEF inventory on hand than is necessary to meet forecasted demand. Although the current SPECTRACEF inventory has a 26-month shelf life, if demand does not meet or exceed Cornerstone s forecast over the next 20 months, Cornerstone may be required to take a charge against its reserves for obsolete inventory.

Cornerstone s ability to maintain optimal inventory levels also depends on the performance of its third-party contract manufacturers. If Cornerstone is unable to manufacture and release its inventory on a timely and consistent basis, if it fails to maintain an adequate level of product inventory, if its inventory is destroyed or damaged or if its inventory reaches its expiration date, patients might not have access to its products, Cornerstone s reputation and its brands could be harmed and physicians may be less likely to prescribe Cornerstone s products in the future, each of which could have a material adverse effect on Cornerstone s financial condition, results of operations and cash flows.

***If Cornerstone s third-party manufacturers and packagers do not obtain the necessary quota for procurement of controlled substances needed to supply it with its currently marketed products or the quotas are not sufficient, Cornerstone may be unable to meet commercial demand for the products.***

ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D and RESPIVENT-D contain pseudoephedrine, and BALACET 325, APAP 325 and APAP 500 contain propoxyphene, each of which are active pharmaceutical ingredients that are regulated by the U.S. Drug Enforcement Administration, or DEA, under the Controlled Substances Act and are subject to annual manufacturing quotas established by the DEA. Cornerstone depends on Bayer and Sovereign, the manufacturers of bulk tablets for ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D and RESPIVENT-D, Legacy Pharmaceutical Packaging, LLC, or Legacy, and Carton Service, Inc., or Carton Service, the manufacturers of trade and sample packaging for ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D and RESPIVENT-D, and Vintage Pharmaceuticals, LLC, or Vintage, the manufacturer of BALACET 325, APAP 325 and

APAP 500, to obtain the necessary quotas from the DEA to procure active pharmaceutical ingredients and to supply and package finished product to meet its demand. The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas to manufacturers. Although Cornerstone has adopted a production planning program in an effort to

Table of Contents

minimize the risks associated with shortages of these products, unexpected market requirements or problems with third-party facilities, among other factors, could result in shortages of one or more of these products. If Cornerstone s commercial requirements of its products exceed the applicable DEA quotas, its suppliers and contract manufacturers would need to apply to the DEA for a quota adjustment. The DEA has substantial discretion in determining whether to make any such adjustment and may decide not to do so. In addition, Cornerstone is subject to strict regulatory restrictions on its handling, sale and distribution of its controlled substance products, including security, recordkeeping and reporting obligations enforced by the DEA. Cornerstone s failure to comply with these requirements could result in the loss of its DEA registration, significant restrictions on its controlled substance products, civil penalties or criminal prosecution.

***Product liability lawsuits against Cornerstone could cause it to incur substantial liabilities and to limit commercialization of any products that it may develop.***

Cornerstone faces an inherent risk of product liability exposure related to the sale of its currently marketed products, any other products that it successfully develops and the testing of its product candidates in human clinical trials. If Cornerstone cannot successfully defend itself against claims that its products or product candidates caused injuries, it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for Cornerstone s products or any products that it may develop;

injury to Cornerstone s reputation;

the withdrawal of clinical trial participants;

the withdrawal of a product from the market;

costs to defend the related litigation;

substantial monetary awards to clinical trial participants or patients;

diversion of management time and attention;

loss of revenue; and

Cornerstone s inability to commercialize the products that it may develop.

For example, Cornerstone could face product liability exposure related to the potential toxicity and addictiveness of propoxyphene. Propoxyphene is one of two active pharmaceutical ingredients, together with acetaminophen, in BALACET 325, APAP 325 and APAP 500. The consumer advocacy organization Public Citizen filed suit in June 2008 against the FDA based on the FDA s failure to act on Public Citizen s February 2006 citizen petition that had requested that the FDA immediately begin the phased removal of all drugs containing propoxyphene from the marketplace based on propoxyphene s toxicity relative to its efficacy and its tendency to induce psychological and physical dependence. In addition, in December 2006, the FDA recognized concerns about the known liver toxicity of over-the-counter pain relievers, including acetaminophen, which is found in BALACET 325, APAP 325 and APAP 500. While Cornerstone is not aware of any pending or threatened product liability claims against Cornerstone related to propxyphene or acetaminophen, there can be no assurance that such claims will not arise in the future.

Cornerstone s contracts with wholesalers and other customers require it to carry product liability insurance. Cornerstone has product liability insurance coverage with a $5 million annual aggregate limit and a $5 million

individual claim limit, and which is subject to a per claim deductible and a policy aggregate deductible. The annual cost of this products liability insurance was approximately $138,000 for the policy year beginning September 13, 2007. The amount of insurance that it currently holds may not be adequate to cover all liabilities that it may incur. Insurance coverage is increasingly expensive. Cornerstone may not be able to maintain insurance coverage at a reasonable cost and may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Table of Contents

**Risks Relating to Product Development and Regulatory Matters**

***If Cornerstone is unable to develop safe and efficacious formulations of its product candidates, or its clinical trials for the SPECTRACEF Suspension line extension or its other product candidates are not successful, it may not be able to develop, obtain regulatory approval for and commercialize these product candidates successfully.***

Cornerstone s product candidates are still in various stages of development. Cornerstone s product development pipeline includes the following three SPECTRACEF line extensions: SPECTRACEF 400 mg, a 400 mg dose tablet; SPECTRACEF Once Daily, a once daily dosage tablet; and SPECTRACEF Suspension, an oral suspension for the pediatric market. Cornerstone s product development pipeline also includes the following three additional product candidates: CBP 058, a methscopolamine and antihistamine combination product candidate for the treatment of symptoms of allergic rhinitis; CBP 067, an extended-release antitussive, or cough suppressant, combination product candidate; and CBP 069, also an extended-release antitussive combination product candidate. Except for SPECTRACEF 400 mg, for which the FDA approved Cornerstone s supplemental new drug application, or sNDA, in July 2008 all of Cornerstone s product candidates remain subject to pharmaceutical formulation development and clinical testing necessary to obtain the regulatory approvals or clearances required for commercial sale. Depending on the nature of the product candidate, to demonstrate a product candidate s safety and efficacy, Cornerstone and its collaborators generally must either demonstrate bioequivalence with a drug already approved by the FDA or complete human clinical trials. Cornerstone may not be able to obtain permission from the FDA, institutional review boards, or IRBs, or other authorities to commence or complete necessary clinical trials. If permitted, such clinical testing may not prove that Cornerstone s product candidates are safe and effective to the extent necessary to permit it to obtain marketing approvals or clearances from regulatory authorities. One or more of its product candidates may not exhibit the expected therapeutic results in humans, may cause harmful side effects or may have other unexpected characteristics that may delay or preclude submission and regulatory approval or clearance or limit commercial use if approved or cleared. For example, Cornerstone s cough suppressant product candidates, CBP 067 and CBP 069, contain hydrocodone, which has been associated with abuse and can lead to serious illness, injury or death if improperly used. Furthermore, Cornerstone, one of its collaborators, IRBs or regulatory agencies may order a clinical hold or suspend or terminate clinical trials at any time if it is believed that the subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons.

For example, Guidance for Industry issued by the FDA in 2007 regarding, among other things, the design of clinical trials of drug candidates for the treatment of acute bacterial otitis media, noted that investigators or IRBs may consider a placebo-controlled study to be unethical where the trial would involve the withholding of known effective antimicrobial treatment to the placebo control group unless the investigators and IRBs determine that the withholding of known effective treatment would result in no more than a minor increase over minimal risk. The FDA suggested that the ethical dilemma might be bridged by using a superiority study of the investigational antimicrobial compared to a known effective antimicrobial treatment. While the FDA did not absolutely prohibit placebo-controlled trials in such cases, Cornerstone believes this FDA guidance may make placebo-controlled trials more difficult to design and complete, especially in pediatric populations.

Adverse or inconclusive clinical trial results concerning any of Cornerstone s product candidates could require it to conduct additional clinical trials, result in increased costs and significantly delay the submission for marketing approval or clearance for such product candidates with the FDA or other regulatory authorities or result in failure to obtain approval or approval for a narrower indication. If clinical trials fail, Cornerstone s product candidates would not receive regulatory approval or achieve commercial viability.

***If clinical trials for Cornerstone s product candidates are delayed, Cornerstone would be unable to obtain regulatory approval and commercialize its product candidates on a timely basis, which would require it to incur additional costs and delay the receipt of any revenues from product sales.***

Cornerstone currently expects to commence a clinical trial with respect to SPECTRACEF Once Daily in the fourth quarter of 2008, SPECTRACEF Suspension in 2009 for acute otitis media, its methscopolamine/antihistamine product candidate CBP 058 in the first quarter of 2009 and its hydrocodone cough suppressant product candidates CBP 067 and CBP 069 in 2009. Cornerstone cannot predict whether it will encounter

Table of Contents

problems with any of its completed or planned clinical trials that will delay or cause regulatory authorities, IRBs or Cornerstone to suspend those clinical trials or the analysis of data from such trials.

Any of the following could delay the completion of Cornerstone s planned clinical trials:

- discussions with the FDA regarding the scope or design of its clinical trials;
- delay in obtaining, or the inability to obtain, required approvals from regulators, IRBs or other governing entities at clinical sites selected for participation in its clinical trials;
- the number of patients required for its clinical trials may be larger than it anticipates, enrollment in its clinical trials may be slower than it anticipates or participants may drop out of its clinical trials at a higher rate than it anticipates;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- its clinical trials may produce negative or inconclusive results, and it may decide, or regulators may require it, to conduct additional clinical trials, or it may abandon projects that had appeared to be promising;
- its third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner;
- insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct its clinical trials;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical investigation;
- serious and unexpected drug-related side effects experienced by participants in past clinical trials for the same or a different indication; or
- exposure of participants to unacceptable health risks.

Cornerstone s ability to enroll patients in its clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the seasonality of the disease, the availability of effective treatments for the relevant disease, competing trials with other product candidates and the eligibility criteria for the clinical trial. Delays in patient enrollment can result in increased costs and longer development times. In addition, subjects may drop out of Cornerstone s clinical trials and thereby impair the validity or statistical significance of the trials. Delays in patient enrollment and the related increase in costs also could cause Cornerstone to decide to discontinue a clinical trial prior to completion.

Cornerstone expects to rely on academic institutions and contract research organizations to supervise or monitor some or all aspects of the clinical trials for the product candidates it advances into clinical testing. Accordingly, Cornerstone has less control over the timing and other aspects of these clinical trials than if it conducted them entirely on its own.

Although Cornerstone has not previously experienced the foregoing risks with respect to its clinical trials, as a result of these risks, Cornerstone or third parties on whom it relies may not successfully begin or complete Cornerstone s clinical trials in the time periods forecasted, if at all. If the results of Cornerstone s planned clinical trials for its product candidates are not available when it expects or if Cornerstone encounters any delays in the analysis of data from its clinical trials, it may be unable to submit results for regulatory approval or clearance or conduct additional clinical

trials on the schedule it anticipates.

If clinical trials are delayed, the commercial viability of Cornerstone s product candidates may be reduced. If Cornerstone incurs costs and delays in its programs, or if Cornerstone does not successfully develop and commercialize its products, its future operating and financial results will be materially affected.

***If Cornerstone s clinical trials do not demonstrate safety and efficacy in humans, Cornerstone may experience delays, incur additional costs and ultimately be unable to commercialize its product candidates.***

Depending upon the nature of the product candidate, obtaining regulatory approval for the sale of its product candidates may require Cornerstone and its collaborators to fund and conduct clinical trials to demonstrate the

safety and efficacy of Cornerstone s product candidates in humans. Clinical testing is expensive, difficult to design and implement, uncertain as to outcome and, depending on the design of the trial, takes several years or more to complete. Clinical data is often susceptible to varying interpretations, and many companies that have believed their products performed satisfactorily in clinical trials were nonetheless unable to obtain FDA approval for their product candidates. Similarly, even if clinical trials of a product candidate are successful in one indication, clinical trials of that product candidate for other indications may be unsuccessful. One or more of Cornerstone s clinical trials could fail at any stage of testing.

Cornerstone expects to submit an NDA to the FDA in 2009 for SPECTRACEF Suspension for use of this product candidate by children with pharyngitis or tonsillitis. TAP Pharmaceuticals, Inc., or TAP, conducted all of the preclinical studies and clinical trials of the oral suspension formulation of SPECTRACEF before Cornerstone licensed the rights to SPECTRACEF from Meiji. Cornerstone intends to rely on the results of these prior clinical trials to support its NDA for SPECTRACEF Suspension. TAP conducted its clinical trials of the oral suspension formulation of SPECTRACEF using a non-inferiority design, meaning that the objective was to demonstrate that the safety and effectiveness of SPECTRACEF Suspension is not inferior relative to the control drug. However, current FDA guidelines request superiority design clinical trials, meaning that the objective of the clinical trials is to demonstrate that the test drug s safety and effectiveness are superior to the control drug. If the FDA does not permit Cornerstone to rely on the prior clinical data for SPECTRACEF Suspension, Cornerstone would be required to repeat some or all of the clinical trials, which would lead to unanticipated costs and delays. Problems with the previous trials, such as incomplete, outdated or otherwise unacceptable data also could cause Cornerstone s NDA for this indication to be delayed or rejected.

If Cornerstone is required to conduct additional clinical trials or other testing of its product candidates in addition to those that it currently contemplates, if it is unable to successfully complete its clinical trials or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, Cornerstone may:

- be delayed in obtaining marketing approval for its product candidates;
- not be able to obtain marketing approval;
- obtain approval for indications that are not as broad as intended; or
- have the product removed from the market after obtaining marketing approval.

Cornerstone s product development costs also will increase if it experiences delays in testing or obtaining approvals. Significant clinical trial delays also could shorten the patent protection period during which Cornerstone may have the exclusive right to commercialize its product candidates or allow its competitors to bring products to market before it does and impair Cornerstone s ability to commercialize its products or product candidates.

***If Cornerstone is not able to obtain required regulatory approvals, Cornerstone will not be able to commercialize its product candidates, and its ability to generate revenue will be materially impaired.***

Cornerstone s product candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, the DEA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent Cornerstone from commercializing the product candidate. To obtain FDA approval, Cornerstone must provide the FDA with data demonstrating to the FDA s satisfaction that the product is safe

and effective for each of its intended uses and that the product can be consistently manufactured to meet FDA quality standards and requirements. The amount and type of data required will depend on the type of approval required or available for a particular product candidate. The most stringent requirements apply to NDA approvals, which require extensive safety and efficacy data from adequate and well controlled clinical trials. Products that are essentially identical to FDA-listed and NDA-approved drugs may be approved under an ANDA with proof of bioequivalence to the reference listed drug and a showing that the product candidate is the same as an already-approved drug in terms of active pharmaceutical ingredients, indications for use, labeling, dosage strength, dosage form and route of administration, in lieu of clinical trials. In addition, products approved based on the submission of an NDA

Table of Contents

under Section 505(b)(2) of the FDCA by relying, in part, on findings of safety and efficacy of a similar previously approved product may or may not require additional clinical testing. In all cases, securing FDA approval also requires the submission of information about the product manufacturing process to, and inspection of the manufacturing facilities by, the FDA. Cornerstone s future products may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities, manufacturing flaws, or other characteristics that may preclude Cornerstone from obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved and the nature of the disease or condition to be treated. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations or medical and technical developments during the review process may delay the approval or cause the rejection of an application. The FDA has substantial discretion in the approval process and may require additional clinical or other data as a condition of reviewing or approving an application. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval Cornerstone ultimately obtains may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

***Cornerstone s limited experience in obtaining regulatory approvals could delay, limit or prevent such approvals for its product candidates.***

Cornerstone has only limited experience in preparing and submitting the applications necessary to gain regulatory approvals and expects to rely on third-party contract research organizations to assist it in this process. Cornerstone acquired the rights to most of its currently marketed products and product candidates through two licensing transactions, one for ALLERX in February 2005 and the other for SPECTRACEF in October 2006. Except for SPECTRACEF 400 mg, for which the FDA approved Cornerstone s sNDA in July 2008, Cornerstone has not received approval from the FDA for any of its products or demonstrated its ability to obtain regulatory approval for any drugs that it has developed or is developing. Cornerstone s limited experience in this regard could delay or limit approval of its product candidates if it is unable to effectively manage the applicable regulatory process with either the FDA or foreign regulatory authorities. In addition, significant errors or ineffective management of the regulatory process could prevent approval of a product candidate, especially given the substantial discretion that the FDA and foreign regulatory authorities have in this process.

***Some of Cornerstone s specialty pharmaceutical products are now being marketed without approved NDAs or ANDAs.***

Even though the FDCA requires pre-marketing approval of all new drugs, as a matter of history and regulatory policy, the FDA has historically refrained from taking enforcement action against some marketed, unapproved new drugs. Specifically, some marketed prescription and nonprescription drugs are not the subject of an approved marketing application because they are thought to be identical, related, or similar to historically-marketed products, which were thought not to require pre-market review and approval, or which were approved only on the basis of safety, at the time they entered the marketplace. Many such drugs, including some cough, cold and allergy drugs like the ALLERX and RESPIVENT lines of products and some antispasmodic drugs like the HYOMAX line of products, are marketed under FDA enforcement policies established in connection with the FDA s DESI program, which was established to determine the effectiveness of drug products approved before 1962. Prior to 1962, the FDCA required proof of safety but not efficacy for new drugs. Drugs that were not subject to applications approved between 1938 and 1962 were not subject to DESI review. For a period of time, the FDA permitted these drugs to remain on the market without approval. In 1984, the FDA created a program, known as the Prescription Drug Wrap-Up, also known as DESI II, to address these remaining unapproved drugs. Most of these drugs contain active pharmaceutical ingredients that were

first marketed prior to 1938. The FDA asserts that all drugs subject to the Prescription Drug Wrap-Up are on the market illegally and are subject to FDA enforcement discretion because all prescription drugs must be the subject of an approved drug application. There are several narrow exceptions. For example, both the

original statutory language of the FDCA and the amendments enacted in 1962 include provisions exempting specified drugs from the new drug requirements. The 1938 clause exempts drugs that were on the market prior to the passage of the FDCA in 1938 and that contain the same representations concerning the conditions of use as they did prior to passage of the FDCA. The 1962 amendments exempt, in specified circumstances, drugs that have the same composition and labeling as they had prior to the passage of the 1962 amendments. The FDA and the courts have interpreted these two exceptions very narrowly. The FDA has adopted a risk-based enforcement policy concerning these unapproved drugs. While all such drugs are considered to require FDA approval, FDA enforcement against such products as unapproved new drugs prioritizes products that pose potential safety risks, lack evidence of effectiveness, prevent patients from seeking effective therapies or are marketed fraudulently. In addition, the FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug requirements against all other drugs within that class that have not been so approved.

As of September 15, 2008, Cornerstone s only products that are subject to approved NDAs or ANDAs are SPECTRACEF, BALACET 325, APAP 325 and APAP 500. Cornerstone s net revenues from the sale of unapproved products were $15.4 million, or 55% of total net revenues, in the year ended December 31, 2007, and $17.9 million, or 76% of total net revenues, in the six months ended June 30, 2008. All of Cornerstone s other products are marketed in the United States without an FDA-approved marketing application because they have been considered by Cornerstone to be identical, related or similar to products that have existed in the market without an NDA or ANDA. These products are marketed subject to the FDA s regulatory discretion and enforcement policies, and it is possible that the FDA could disagree with Cornerstone s determination that one or more of these products is identical, related or similar to products that have existed in the marketplace without an NDA or ANDA. If the FDA were to disagree with Cornerstone s determination, it could ask for or require the removal of Cornerstone s unapproved products from the market. While the FDA generally provides sponsors with a one-year grace period during which time they are permitted to continue selling the unapproved drug, it is not statutorily required to do so and could ask or require that the products be removed from the market immediately. If the FDA required Cornerstone to remove its unapproved products from the market, particularly its ALLERX Dose Pack family of products and its HYOMAX line of products, Cornerstone s revenue from product sales would be significantly reduced.

For example, if the FDA issues an approved NDA for one of the drug products within the class of drugs that includes ALLERX or completes the efficacy review for that drug product, it may require Cornerstone to also file an NDA or ANDA application for its ALLERX products in order to continue marketing them in the United States. Although Cornerstone may be given the benefit of a grace period to submit a marketing application before the agency would take enforcement action, the time it takes Cornerstone to complete the necessary clinical trials and submit an NDA or ANDA to the FDA may exceed this time period, which would result in an interruption of sales of ALLERX. If the FDA asks or requires that the ALLERX products be removed from the market, Cornerstone s financial condition and results of operations would be materially and adversely affected. Cornerstone s net revenues from sales of its ALLERX products were $14.2 million in the year ended December 31, 2007 and $12.9 million in the six months ended June 30, 2008. Cornerstone filed an IND with the FDA in 2007 for a respiratory product containing methscopolamine, one of the APIs in all ALLERX Dose Pack products. A similar result would apply if the FDA issued an approved NDA for one of the drug products within the class of drugs that includes the HYOMAX products or completed the efficacy review for that drug product and required other manufacturers to also file an NDA or ANDA for their products in order to continue marketing them in the United States. Cornerstone s net revenues from sales of its HYOMAX products, which it launched beginning in May 2008, were $4.5 million in the six months ended June 30, 2008. When the FDA announced in May 2007 that it was directing that all non-approved extended release guaifenesin products, including Cornerstone s Deconsal®, or DECONSAL, II product, be removed from the market within 180 days, it noted that Adams Respiratory Therapeutics, Inc., or Adams, was the only company to date that had obtained FDA approval for timed-release products containing guaifenesin. Cornerstone s net revenues from sales of Deconsal II were $177,000 in 2007 and $1.2 million in 2006.

71

Table of Contents

***Cornerstone s sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement could result in decreased use or sales of its products.***

Cornerstone s sales of its currently marketed products are, and any future sales of its product candidates will be, dependent, in part, on the availability of coverage and reimbursement from third-party payors, including government health care programs such as Medicare and Medicaid, and private insurance plans. All of Cornerstone s products are generally covered by managed care and private insurance plans. The status or tier within each plan varies but coverage is similar to other products within the same class of drugs. For example, SPECTRACEF is covered by private insurance plans similar to other marketed, branded cephalosporins. Some Medicare Part D plans also cover some or all of Cornerstone s products, but the amount and level of coverage varies from plan to plan. Cornerstone also participates in the Medicaid Drug Rebate program with the Centers for Medicare & Medicaid Services and submits all of its products for inclusion in this program. Coverage of Cornerstone s products under individual state Medicaid plans varies from state to state.

There have been, there are and Cornerstone expects there will continue to be federal and state legislative and administrative proposals that could limit the amount that government health care programs will pay to reimburse the cost of pharmaceutical and biologic products. For example, the MMA created a new Medicare benefit for prescription drugs. More recently, the Deficit Reduction Act of 2005 significantly reduced reimbursement for drugs under the Medicaid program. Legislative or administrative acts that reduce reimbursement for Cornerstone s products could adversely impact its business. In addition, private insurers, such as MCOs, may adopt their own reimbursement reductions in response to federal or state legislation. Any reduction in reimbursement for Cornerstone s products could materially harm its results of operations. In addition, Cornerstone believes that the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of its products, which may adversely impact its product sales. Furthermore, when a new product is approved, governmental and private coverage for that product, and the amount for which that product will be reimbursed, are uncertain. Cornerstone cannot predict the availability or amount of reimbursement for its product candidates, and current reimbursement policies for marketed products may change at any time.

The MMA established a voluntary prescription drug benefit, called Part D, that became effective in 2006 for all Medicare beneficiaries. Cornerstone cannot be certain that its currently marketed products will continue to be, or any of its product candidates still in development will be, included in the Medicare prescription drug benefit. Even if Cornerstone s products are included, the private health plans that administer the Medicare drug benefit can limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class. In addition, private managed care plans and other government agencies continue to seek price discounts. Because many of these same private health plans administer the Medicare drug benefit, they have the ability to influence prescription decisions for a larger segment of the population. In addition, certain states have proposed or adopted various programs under their Medicaid programs to control drug prices, including price constraints, restrictions on access to certain products and bulk purchasing of drugs.

If Cornerstone succeeds in bringing additional products to the market, these products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow it to sell its product candidates on a competitive basis to a sufficient patient population. Because Cornerstone s product candidates are in the development stage, it does not know whether payors will cover the products and the level of reimbursement, if any, it will receive for these product candidates if they are successfully developed, and is unable at this time to determine the cost-effectiveness of these product candidates. Cornerstone may need to conduct expensive pharmacoeconomic trials in order to demonstrate the cost-effectiveness of its products. Sales of prescription drugs are highly dependent on the availability and level of reimbursement to the consumer from third-party payors, such as government and private insurance plans. These third-party payors frequently require that drug companies provide them with predetermined discounts or rebates from list prices, and third-party payors are increasingly challenging the

prices charged for medical products. If the reimbursement Cornerstone receives for any of its product candidates is inadequate in light of its development and other costs, its ability to realize profits from the affected product candidate would be limited. If reimbursement for Cornerstone s marketed products changes adversely or if it fails to obtain adequate reimbursement for its other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of its products or cause it to reduce the price of its products.

Table of Contents

***If Cornerstone fails to comply with post-approval regulatory requirements for its products or if it experiences unanticipated problems with its marketed products, the FDA may take regulatory actions detrimental to Cornerstone s business, resulting in temporary or permanent interruption of distribution, withdrawal of products from the market or other penalties.***

Cornerstone s FDA-approved products and related operations will be subject to comprehensive post-approval regulation by the FDA. Post-approval requirements include submissions of safety and other post-marketing information; record-keeping and reporting; annual registration of manufacturing facilities and listing of products with the FDA; ongoing compliance with current Good Manufacturing Practice, or cGMP, regulations; and requirements regarding the distribution of samples to physicians and related recordkeeping. Additional, potentially costly, requirements may apply to specific products as a condition of FDA approval or subsequent regulatory developments. Discovery of previously unknown problems with Cornerstone s products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in:

withdrawal of the products from the market;

restrictions on the marketing or distribution of such products;

restrictions on the manufacturers or manufacturing processes;

warning letters;

refusal to approve pending applications or supplements to approved applications that Cornerstone submits;

recalls;

fines;

suspension or withdrawal of regulatory approvals;

refusal to permit the import or export of its products;

product seizures; or

injunctions or the imposition of civil or criminal penalties.

Any of these actions could have a material adverse effect on Cornerstone s business, financial condition and results of operations.

***State pharmaceutical marketing and promotional compliance and reporting requirements may expose Cornerstone to regulatory and legal action by state governments or other government authorities.***

In recent years, several states, including California, Maine, Minnesota, Nevada, New Mexico, Vermont and West Virginia, as well as the District of Columbia, have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs and file periodic reports with the state on sales, marketing, pricing, reporting and other activities. For example, a California statute effective July 1, 2005 requires pharmaceutical companies to adopt and post on their public web site a comprehensive compliance program that complies with the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals and the Office of Inspector General of the Department of Health and Human Services Compliance Program Guidance for

Pharmaceutical Manufacturers. In addition, such a compliance program must establish a specific annual dollar limit on gifts or other items given to individual health care professionals in California.

Other states have also enacted statutes of varying scope that impose reporting and disclosure requirements on pharmaceutical companies pertaining to drug pricing and payments and costs associated with pharmaceutical marketing, advertising and promotional activities, as well as restrictions upon the types of gifts that may be provided to health care practitioners. Similar legislation is being considered in a number of other states. Many of these requirements are new and have not been definitively interpreted by state authorities or courts, and available guidance is limited. Unless and until Cornerstone is in full compliance with these laws, it could face enforcement action and fines and other penalties, and could receive adverse publicity, all of which could materially harm its business.

Table of Contents

***Recently enacted legislation may make it more difficult and costly for Cornerstone to obtain regulatory approval of its product candidates and to produce, market and distribute its existing products.***

On September 27, 2007, President Bush signed the FDAAA into law. The FDAAA grants a variety of new powers to the FDA, many of which are aimed at improving drug safety and assuring the safety of drug products after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While Cornerstone expects the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as its business, will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products.

***Cornerstone may be subject to investigations or other inquiries concerning its compliance with reporting obligations under federal health care program pharmaceutical pricing requirements.***

There have been a number of government enforcement actions under the federal health care programs, primarily Medicare and Medicaid, against numerous pharmaceutical companies alleging that the reporting of prices for pharmaceutical products has resulted in false and overstated prices, such as average wholesale and best price, which are alleged to have improperly inflated the reimbursements paid by Medicare, state Medicaid programs and other payors to health care providers who prescribed and administered those products or pharmacies that dispensed those products. These actions have been brought by both the federal government and individual states. Failure to comply with these government health care program pharmaceutical pricing requirements may lead to federal or state investigations, criminal or civil liability, exclusion from government health care programs, contractual damages and otherwise materially harm Cornerstone s reputation, business and prospects.

***Cornerstone s corporate compliance and corporate governance programs cannot guarantee that it is in compliance with all potentially applicable regulations.***

The development, manufacturing, pricing, marketing, sales and reimbursement of Cornerstone s products and product candidates, together with Cornerstone s general operations, are subject to extensive regulation by federal, state and other authorities within the United States. Cornerstone is a relatively small company and had approximately 83 employees as of September 15, 2008. Cornerstone has developed and instituted a corporate compliance program designed to comply with current best practices for pharmaceutical companies and continues to update the program in response to newly implemented and changing regulatory requirements. However, Cornerstone s compliance program does not and cannot guarantee that the company is in compliance with all potentially applicable federal and state regulations. If Cornerstone fails to comply with any of these regulations, it may be subject to a range of enforcement actions, including significant fines, litigation or other sanctions. Any action against Cornerstone for a violation of these regulations, even if it successfully defends against such actions, could cause it to incur significant legal expenses, divert its management s attention and harm its reputation.

***Cornerstone s relationships with customers and payors are subject to applicable fraud and abuse and other health care laws and regulations, which could expose it to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.***

Health care providers, physicians and others play a primary role in the recommendation and prescription of Cornerstone s products. Cornerstone s arrangements with third-party payors and customers may expose it to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which it will market, sell and distribute its products. Applicable federal and state health care laws and regulations, include, but are not limited to, the following:

The federal anti-kickback statute is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay or to solicit or receive, direct or indirect remuneration, in order to induce business reimbursed under a federal health care program, including Medicare and Medicaid;

Table of Contents

The federal Statute on Limitations of Certain Physician Referrals, commonly referred to as the Stark Law, prohibits physician referrals for designated health services to entities in which the referring physician or an immediate family member has a financial interest, either through an ownership or investment interest or a compensation arrangement, unless the arrangement falls within a specific exception;

The federal False Claims Act imposes liability on any person who knowingly submits, or causes another person or entity to submit, a false claim for payment of government funds. Penalties include three times the government s damages plus civil penalties of $5,500 to $11,000 per false claim. In addition, the False Claims Act permits a person with knowledge of fraud, referred to as a *qui tam* plaintiff, to file a lawsuit on behalf of the government against the person or business that committed the fraud. If the action is successful, the *qui tam* plaintiff is rewarded with a percentage of the recovery;

HIPAA imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

The Social Security Act contains numerous provisions allowing the imposition of a civil money penalty, a monetary assessment, exclusion from the Medicare and Medicaid programs, or some combination of these penalties; and

Many states have analogous state laws and regulations, such as state anti-kickback and false claims laws. In some cases, these state laws impose more strict requirements than the federal laws. Some state laws also require pharmaceutical companies to comply with certain price reporting and other compliance requirements.

Efforts to help ensure that Cornerstone s business arrangements comply with these extensive federal and state health care fraud and abuse laws could be costly. It is possible that governmental authorities may conclude that Cornerstone s business practices do not comply with current or future statutes or regulations involving applicable fraud and abuse or other health care laws and regulations. If Cornerstone s past or present operations, including activities conducted by its sales team or agents, are found to be in violation of any of these laws or any other applicable governmental regulations, Cornerstone may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government health care programs and the curtailment or restructuring of its operations. If any of the physicians or other providers or entities with whom Cornerstone does business is found not to be in compliance with applicable laws, they may also be subject to criminal, civil or administrative sanctions, including exclusions from government health care programs.

Many aspects of these laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations, which increases the risk of potential violations. In addition, these laws and their interpretations are subject to change. Any action against Cornerstone for violation of these laws, even if Cornerstone successfully defends against the action, could cause Cornerstone to incur significant legal expenses, divert Cornerstone management s attention from the operation of its business and damage its reputation.

***Recent proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could force Cornerstone to lower the prices of its products and impair its ability to derive revenue from its products.***

Legislation has been introduced in the United States Congress that, if enacted, would permit more widespread re-importation of FDA-approved drugs from foreign countries into the United States. This could include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. While

Cornerstone does not currently sell any of its products outside the United States, legislation or other factors that increase such sales by Cornerstone s direct competitors could adversely affect Cornerstone s pricing and revenues Alternatively, in response to legislation such as this, Cornerstone might elect not to seek approval for or market its products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue Cornerstone generates from its product sales.

Table of Contents

**Risks Relating to Intellectual Property and Licenses**

***If Cornerstone is unable to obtain and maintain protection for the intellectual property relating to its technology and products, the value of its technology and products will be adversely affected.***

Cornerstone s success depends in part on its ability to obtain and maintain protection for the intellectual property covering or incorporated into its technology and products, whether such technology is owned by Cornerstone or licensed to it by third parties. Patent protection in the pharmaceutical field is highly uncertain and involves complex legal and scientific questions. Cornerstone and its licensors may not be able to obtain additional issued patents relating to their respective technology or products. Even if issued, patents issued to Cornerstone or its licensors may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit Cornerstone s ability to stop competitors from marketing similar products or limit the longevity of the patent protection Cornerstone may have for its products. For example, two U.S. patents exclusively licensed to Cornerstone have been challenged by third parties in re-examination proceedings before the U.S. Patent and Trademark Office. While Cornerstone no longer relies on one of the patents to protect any of its products, Cornerstone believes that the other U.S. patent being re-examined, U.S. patent 6,843,372, or the 372 Patent, covers ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30. If the United States Patent and Trademark Office invalidates some or all of the claims under the 372 Patent, Cornerstone s sales of the ALLERX family of products and its future operating and financial results could be adversely affected. These re-examination proceedings are more fully discussed in the section entitled Cornerstone s Business Legal Proceedings beginning on page 232 of this proxy statement/prospectus. Additionally, changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of Cornerstone s intellectual property or narrow the scope of its patent protection.

Cornerstone s owned or licensed patents also may not afford it protection against competitors with similar technology. Because patent applications in the United States and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither Cornerstone nor its licensors can be certain that it or they were the first to make the inventions claimed in Cornerstone s or their issued patents or pending patent applications, or that Cornerstone or they were the first to file for protection of the inventions set forth in these patent applications. If a third party has also filed a U.S. patent application covering Cornerstone s product candidates or a similar invention, Cornerstone may have to participate in an adversarial proceeding, known as an interference, declared by the United States Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that Cornerstone s efforts could be unsuccessful, resulting in a loss of its U.S. patent protection. In addition, patents generally expire, regardless of the date of issue, 20 years from the earliest claimed non-provisional filing date. Cornerstone is not able to accurately predict the remaining lengths of the applicable patent term following regulatory approval of any of its product candidates.

Some of Cornerstone s currently marketed products do not have patent protection and in most cases such products face generic competition. In addition, although Cornerstone owns or exclusively licenses U.S. patents and patent applications with claims directed to the pharmaceutical formulations of its product candidates, methods of use of its product candidates to treat particular conditions, delivery systems for its product candidates, delivery profiles of its product candidates and methods for producing its product candidates, patent protection is not available for composition of matter claims directed to the active pharmaceutical ingredients of any of Cornerstone s products or product candidates other than SPECTRACEF and the SPECTRACEF line extensions. The SPECTRACEF composition of matter patent expires in April 2009.

Cornerstone s collaborators and licensors may not adequately protect its intellectual property rights. These third parties may have the first right to maintain or defend Cornerstone s intellectual property rights and, although Cornerstone may

have the right to assume the maintenance and defense of its intellectual property rights if these third parties do not, Cornerstone s ability to maintain and defend its intellectual property rights may be compromised by the acts or omissions of these third parties. For example, under Cornerstone s license arrangement with Pharmaceutical Innovations, LLC, or Pharmaceutical Innovations, for ALLERX Dose Pack and ALLERX Dose Pack PE, Pharmaceutical Innovations generally is responsible for prosecuting and

Table of Contents

maintaining patent rights, although Cornerstone has the right to support the continued prosecution or maintenance of the patent rights if Pharmaceutical Innovations fails to do so. In addition, both Pharmaceutical Innovations and Cornerstone have the right to pursue claims against third parties for infringement of the patent rights.

***The composition of matter patent for the API in SPECTRACEF and in Cornerstone s SPECTRACEF line extension product candidates will expire in April 2009, and none of Cornerstone s other products or product candidates have, or will have, composition of matter patent protection.***

Cornerstone s products other than SPECTRACEF and product candidates other than the SPECTRACEF line extensions lack composition of matter protection for the API, and because the composition of matter patent for SPECTRACEF expires in April 2009, competitors will be able to offer and sell products with the same API as Cornerstone s products so long as these competitors do not infringe any other patents that Cornerstone or third parties hold, including formulation and method of use patents. However, method of use patents, in particular, are more difficult to enforce than composition of matter patents because of the risk of off-label sale or use of the subject compounds. Physicians are permitted to prescribe an approved product for uses that are not described in the product s labeling. Although off-label prescriptions may infringe Cornerstone s method of use patents, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. Off-label sales would limit Cornerstone s ability to generate revenue from the sale of its product candidates, if approved for commercial sale. In addition, if a third party were able to design around Cornerstone s formulation and process patents and create a different formulation using a different production process not covered by Cornerstone s patents or patent applications, Cornerstone would likely be unable to prevent that third party from manufacturing and marketing its product.

***Trademark protection of Cornerstone s products may not provide it with a meaningful competitive advantage.***

Cornerstone uses trademarks on most of its currently marketed products and believes that having distinctive marks is an important factor in marketing those products, particularly SPECTRACEF and ALLERX. Distinctive marks may also be important for any additional products that Cornerstone successfully develops and commercially markets. However, Cornerstone generally does not expect its marks to provide a meaningful competitive advantage over other branded or generic products. Cornerstone believes that efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors are and are likely to continue to be more important factors in the commercial success of its products and, if approved, its product candidates. For example, physicians and patients may not readily associate Cornerstone s trademark with the applicable product or API. In addition, prescriptions written for a branded product are typically filled with the generic version at the pharmacy if an approved generic is available, resulting in a significant loss in sales of the branded product, including for indications for which the generic version has not been approved for marketing by the FDA. Competitors also may use marks or names that are similar to Cornerstone s trademarks. If Cornerstone initiates legal proceedings to seek to protect its trademarks, the costs of these proceedings could be substantial and it is possible that its efforts could be unsuccessful.

Competitors may also seek to cancel Cornerstone s similar trademarks based on the competitor s prior use. For example, on May 15, 2008, the United States Patent and Trademark Office sent written notice to Cornerstone that Bausch & Lomb Incorporated, or Bausch & Lomb, filed a cancellation proceeding with respect to the ALLERX registration, 3,384,232 (serial number 77120121), seeking to cancel the ALLERX registration because of a claim that such registration dilutes the distinctive quality of Bausch & Lomb s Alrex® trademark and that Bausch & Lomb is likely to be damaged by the ALLERX registration. Cornerstone responded to the Trademark Trial and Appeal Board on June 24, 2008 opposing the claims by Bausch & Lomb, but is concurrently engaging in discussions with Bausch & Lomb to seek settlement of the cancellation proceeding on favorable terms. If the settlement discussions do not provide a prior resolution, Cornerstone could take numerous courses of action, including continuing to oppose the claims, undertaking action to cancel Bausch & Lomb s registration of its Alrex® trademark, or entering into discovery.

If the United States Patent and Trademark Office cancels the ALLERX registration, Cornerstone will be required to cease marketing its

Table of Contents

products under that brand, which could adversely affect Cornerstone s sales of the ALLERX family of products and its future operating and financial results.

***If Cornerstone fails to comply with its obligations in its intellectual property licenses with third parties, it could lose license rights that are important to its business.***

Cornerstone has acquired intellectual property rights relating to all of its product candidates under license agreements with third parties and expects to enter into additional licenses in the future. These licenses provide Cornerstone with rights to intellectual property that is necessary for its business. For example, Cornerstone acquired from Meiji the exclusive U.S. rights to market, develop and commercialize SPECTRACEF. Pursuant to its agreement with Meiji, Cornerstone obtained an exclusive license to use know-how and trademarks to commercialize SPECTRACEF and any other pharmaceutical product, such as SPECTRACEF Suspension, containing the API cefditoren pivoxil in the United States.

Cornerstone s existing licenses impose, and Cornerstone expects that future licenses will impose, various obligations related to development and commercialization activities, milestone and royalty payments, sublicensing, patent protection and maintenance, insurance and other similar obligations common in these types of agreements. For example, Cornerstone has entered into an agreement with Neos Therapeutics, L.P., or Neos, and Coating Place, Inc., or Coating Place, directed to commercialization of certain antihistamine and antitussive combination products, which obligates Cornerstone to use commercially reasonable efforts to carry out development and regulatory activities within timelines specified in such development agreement. Under this agreement, Cornerstone is obligated to use commercially reasonable efforts to develop and commercially launch products containing an antihistamine and antitussive in the United States as soon as practicable, and thereafter to maximize sales of such licensed product in the United States. If Cornerstone fails to comply with these obligations or otherwise breaches the license agreement, Neos or Coating Place may have the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against Cornerstone for damages. Any such termination or claim could prevent or impede Cornerstone s ability to market any product that is covered by the licensed patents. Even if Cornerstone contests any such termination or claim and is ultimately successful, Cornerstone could suffer adverse consequences to its operations and business interests.

***If Cornerstone is unable to protect the confidentiality of its proprietary information and know-how, the value of its technology and products could be adversely affected.***

In addition to patented technology, Cornerstone relies upon unpatented proprietary technology, processes and know-how. Cornerstone seeks to protect its unpatented proprietary information in part by confidentiality agreements with its employees, consultants and third parties. These agreements may be breached and Cornerstone may not have adequate remedies for any such breach. In addition, Cornerstone s trade secrets may otherwise become known or may be independently developed by competitors. If Cornerstone is unable to protect the confidentiality of its proprietary information and know-how, competitors may be able to use this information to develop products that compete with Cornerstone s products, which could adversely impact Cornerstone s business.

***If Cornerstone infringes or is alleged to infringe intellectual property rights of third parties, Cornerstone s business will be adversely affected.***

Cornerstone s development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may subsequently issue and to which Cornerstone does not hold a license or other rights. Third parties may own or control these patents or patent applications in the United States and abroad. These third parties could bring claims against Cornerstone or its

collaborators that would cause it to incur substantial expenses and, if such claims are successful, could cause Cornerstone to pay substantial damages. Further, if a patent infringement suit were brought against Cornerstone or its collaborators, it or they could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement or other similar claims or to avoid potential claims, Cornerstone or its potential future collaborators may choose or be required to seek a license from a third party and be required to

Table of Contents

pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if Cornerstone or its collaborators were able to obtain a license, the rights may be nonexclusive, which could result in Cornerstone s competitors gaining access to the same intellectual property. Ultimately, Cornerstone could be prevented from commercializing a product, or be forced to cease some aspect of its business operations, if, as a result of actual or threatened patent infringement claims, it or its collaborators are unable to enter into licenses on acceptable terms. This could harm Cornerstone s business significantly.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against Cornerstone, Cornerstone may become a party to other patent litigation and other proceedings, including interference proceedings declared by the United States Patent and Trademark Office, regarding intellectual property rights with respect to its products and technology. The cost to Cornerstone of any patent litigation or other proceeding, even if resolved in its favor, could be substantial. Some of Cornerstone s competitors may be able to sustain the costs of such litigation or proceedings more effectively than it can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on Cornerstone s ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Many of Cornerstone s employees were previously employed at other pharmaceutical or biotechnology companies, including its competitors or potential competitors. Cornerstone tries to ensure that its employees do not use the proprietary information or know-how of others in their work for Cornerstone. However, Cornerstone may be subject to claims that it or its employees have inadvertently or otherwise used or disclosed the intellectual property, trade secrets or other proprietary information of any such employee s former employer. Cornerstone may be required to engage in litigation to defend against these claims. Even if Cornerstone is successful in such litigation, the litigation could result in substantial costs to Cornerstone or be distracting to its management. If Cornerstone fails to defend or is unsuccessful in defending against any such claims, in addition to paying monetary damages, it may lose valuable intellectual property rights or personnel.

**Risks Relating to Cornerstone s Dependence on Third Parties**

***Cornerstone uses third parties to manufacture all of its products and product candidates. This may increase the risk that it will not have sufficient quantities of its products or product candidates at an acceptable cost, which could result in clinical development and commercialization of its product candidates being delayed, prevented or impaired.***

Cornerstone has no manufacturing facilities and relies on third parties to manufacture and supply all of its products. Cornerstone currently relies on these third parties for the purchase of raw materials and the manufacture and packaging of its products. Many of the agreements Cornerstone has entered into are exclusive agreements in which the manufacturer is a single-source supplier, preventing Cornerstone from using alternative sources. Cornerstone obtains all of its BALACET 325 and APAP 325 supply from Vintage, which has the exclusive right to supply all of Cornerstone s requirements for BALACET 325. Meiji has the exclusive right to supply all of Cornerstone s requirements for cefditoren pivoxil, the API in SPECTRACEF. In addition, Cornerstone s manufacturing agreement with Bayer obligates it to purchase minimum quantities of ALLERX bulk tablets. However, Bayer is not a single-source supplier, and Cornerstone has another supplier that is qualified to manufacture ALLERX. Cornerstone has also qualified two packagers of the ALLERX product line.

If any of the third-party manufacturers with whom Cornerstone contracts fail to perform their obligations, Cornerstone may be adversely affected in a number of ways, including the following:

Cornerstone may not be able to meet commercial demands for ALLERX, BALACET 325, or SPECTRACEF;

Cornerstone may be required to cease distribution or issue recalls;

Cornerstone may not be able to initiate or continue clinical trials of its product candidates that are under development; and

Table of Contents

Cornerstone may be delayed in submitting applications for regulatory approvals for its product candidates.

Cornerstone may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. If Cornerstone were required to change manufacturers for ALLERX, BALACET 325, or SPECTRACEF, it would be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and all applicable regulations and guidelines, including FDA requirements and approved NDA product specifications. In addition, Cornerstone would be required to conduct additional clinical bioequivalence trials to demonstrate that the products manufactured by the new manufacturer are equivalent to the products manufactured by its current manufacturer, which could take 12 to 18 months or possibly longer. The technical transfer of manufacturing capabilities can be difficult. For example, in the second quarter of 2007, Cornerstone initiated the qualification process for two new manufacturing sites for the five different tablet formulations that are used in the various AM/PM dosing combinations in the different ALLERX Dose Pack products in order to have additional manufacturing capacity and to mitigate the risks associated with relying on a single supplier. Both facilities initially encountered difficulties in developing stable tablet formulations, which were later resolved. Any delays associated with the verification of a new manufacturer or conducting additional clinical bioequivalence trials could adversely affect Cornerstone s production schedule or increase its production costs and could ultimately lead to a shortage of supply in the market.

Additionally, FDA regulations restrict the manufacture of penicillin products in the same facility that manufactures a cephalosporin such as SPECTRACEF. These restrictions reduce the number of cGMP FDA-approved facilities that are able to manufacture cephalosporins, which could complicate Cornerstone s ability to quickly qualify a new manufacturer for SPECTRACEF. Cornerstone is aware that Patheon, the owner of the Puerto Rico-based manufacturing plant for SPECTRACEF, is reviewing its strategic alternatives with respect to this plant. Cornerstone s contract for the manufacture of SPECTRACEF is terminable by either party at any time. There is no assurance that a buyer will be interested in continuing the manufacture of SPECTRACEF, which could interrupt the commercial supply and research formulation development of SPECTRACEF and SPECTRACEF line extensions.

Cornerstone relies on third-party manufacturers to purchase the necessary raw materials to manufacture its products, with the exception of cefditoren pivoxil, the API in SPECTRACEF, which Cornerstone is required to purchase from Meiji. In some instances, Cornerstone s third-party manufacturers have encountered difficulties obtaining raw materials needed to manufacture Cornerstone s products as a result of DEA regulations and because of the limited number of suppliers of pseudoephedrine and methscopolamine nitrate. Although these difficulties have not had a material adverse impact on Cornerstone, such problems could have a material adverse impact on Cornerstone in the future. In addition, supply interruptions or delays could occur that require Cornerstone or its manufacturers to obtain substitute materials or products, which would require additional regulatory approvals. Changes in Cornerstone s raw material suppliers could result in delays in production, higher raw material costs and loss of sales and customers because regulatory authorities must generally approve raw material sources for pharmaceutical products. Any significant supply interruption could have a material adverse effect on Cornerstone s business, financial condition and results of operation.

In addition, Cornerstone imports the API for its products from third parties that manufacture the API outside the United States, and Cornerstone expects to import finished product from outside the United States in the future. This may give rise to difficulties in obtaining API or finished product in a timely manner as a result of, among other things, regulatory agency import inspections, incomplete or inaccurate import documentation or defective packaging. For example, the FDA has stated that it will inspect 100% of API and finished product that is imported into the United States. If the FDA requires additional documentation from third-party manufacturers relating to the safety or intended use of the API or finished product, the importation of the API or finished product could be delayed. A delay in the importation of API could, if not remediated, cause a delay in the production of finished product. Any delays in the production or importation of finished product could result in a supply disruption.

Table of Contents

***Cornerstone relies on its third-party manufacturers for compliance with applicable regulatory requirements. This may increase the risk of sanctions being imposed on Cornerstone or on a manufacturer of its products or product candidates, which could result in Cornerstone s inability to obtain sufficient quantities of these products or product candidates.***

Cornerstone s manufacturers may not be able to comply with cGMP regulations or other regulatory requirements or similar regulatory requirements outside the United States. DEA regulations also govern facilities where controlled substances are manufactured. Cornerstone s manufacturers are subject to DEA registration requirements and unannounced inspections by the FDA, the DEA, state regulators and similar regulators outside the United States. Cornerstone s failure, or the failure of its third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on Cornerstone, including:

fines;

injunctions;

civil penalties;

the failure of regulatory authorities to grant marketing approval of Cornerstone s product candidates;

delays, suspension or withdrawal of approvals;

suspension of manufacturing operations;

license revocation;

seizures or recalls of products or product candidates;

operating restrictions; and

criminal prosecutions.

Any of these sanctions could significantly and adversely affect supplies of Cornerstone s products and product candidates.

***Cornerstone relies on third parties to conduct its clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.***

Cornerstone does not independently conduct clinical trials for its product candidates. Cornerstone relies on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Its reliance on these third parties for clinical development activities reduces its control over these activities. Cornerstone is responsible for ensuring that each of its clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires Cornerstone to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Cornerstone s reliance on third parties that it does not control does not relieve it of these responsibilities and requirements. Furthermore, these third parties may also have relationships with other entities, some of which may be Cornerstone s competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct Cornerstone s clinical trials in

accordance with regulatory requirements or its stated protocols, Cornerstone will not be able to obtain, or may be delayed in obtaining, regulatory approvals for its product candidates and will not be able to, or may be delayed in its efforts to, successfully commercialize its product candidates.

***Cornerstone relies on third parties to market and promote some products, and these third parties may not successfully commercialize these products.***

Cornerstone may seek to enter into co-promotion arrangements to enhance its promotional efforts and, therefore, sales of its products. By entering into agreements with pharmaceutical companies that have experienced sales forces with strong management support, Cornerstone can reach health care providers in areas where it has limited or no sales force representation, thus expanding the reach of its sales and marketing programs for its promoted products. Cornerstone also seeks to enter into co-promotion arrangements for the marketing of products that are not aligned with its respiratory focus and, therefore, are not promoted by

Table of Contents

Cornerstone s sales force. For example, in July 2007, Atley Pharmaceuticals began marketing and promoting BALACET 325 to pain specialists and other high prescribers of pain products through a co-promotion agreement. Cornerstone may not be successful in entering into additional marketing arrangements in the future and, even if successful, it may not be able to enter into these arrangements on terms that are favorable to Cornerstone. In addition, Cornerstone may have limited or no control over the sales, marketing and distribution activities of these third parties. If these third parties are not successful in commercializing the products covered by these arrangements, Cornerstone s future revenues may suffer.

***Any collaboration arrangements that Cornerstone may enter into in the future may not be successful, which could adversely affect its ability to develop and commercialize its product candidates.***

Cornerstone has entered into and may in the future enter into collaboration arrangements on a selective basis. Any future collaborations that it enters into may not be successful. The success of its collaboration arrangements will depend heavily on the efforts and activities of its collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or the commercialization of the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration of its collaboration agreements would adversely affect Cornerstone financially and could harm its business reputation.

***The concentration of its product sales to only a few wholesale distributors increases the risk that Cornerstone will not be able to effectively distribute its products if it needs to replace any of these customers, which would cause Cornerstone s sales to decline.***

The majority of Cornerstone s sales are to a small number of pharmaceutical wholesale distributors, which in turn sell Cornerstone s products primarily to retail pharmacies, which ultimately dispense its products to the end consumers. In 2007, Cardinal Health, McKesson and AmerisourceBergen accounted for 91% of Cornerstone s total sales.

If any of these customers cease doing business with Cornerstone or materially reduce the amount of product they purchase from it and Cornerstone is unable to enter into agreements with replacement wholesale distributors on commercially reasonable terms, it might not be able to effectively distribute its products through retail pharmacies. The risk of this occurring is exacerbated by the recent significant consolidation in the wholesale drug distribution industry, including through mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the market.

***Cornerstone s business could suffer as a result of a failure to manage and maintain its distribution network.***

Cornerstone relies on third parties to distribute its products. Cornerstone has contracted with DDN/Obergfel, LLC, or DDN, for the distribution of its products to wholesalers, retail drug stores, mass merchandisers and grocery stores in the United States.

This distribution network requires significant coordination with Cornerstone s supply chain, sales and marketing and finance organizations. Failure to maintain Cornerstone s contract with DDN, or the inability or failure of DDN to adequately perform as agreed under its contract with Cornerstone, could negatively impact Cornerstone. Cornerstone

does not have its own warehouse or distribution capabilities, it lacks the resources and experience to establish any of these functions and it does not intend to establish these functions in the foreseeable future. If Cornerstone were unable to replace DDN in a timely manner in the event of a natural disaster, failure to meet FDA and other regulatory requirements, business failure, strike or any other difficulty affecting DDN, the distribution of its products could be delayed or interrupted, which would damage Cornerstone s results of operations and market position. Failure to coordinate financial systems could also negatively impact Cornerstone s ability to accurately report and forecast product sales and fulfill its regulatory

Table of Contents

obligations. If Cornerstone is unable to effectively manage and maintain its distribution network, sales of its products could be severely compromised and its business could be harmed.

Cornerstone also depends on the distribution abilities of its wholesale customers to ensure that Cornerstone s products are effectively distributed through the supply chain. If there are any interruptions in Cornerstone s customers ability to distribute products through their distribution centers, Cornerstone s products may not be effectively distributed, which could cause confusion and frustration among pharmacists and lead to product substitution. For example, in the fourth quarter of 2007 and the first quarter of 2008, several Cardinal Health distribution centers were placed on probation by the DEA and were prohibited from distributing controlled substances. Although Cardinal Health had a plan in place to re-route all orders to the next closest distribution center for fulfillment, system inefficiency resulted in a failure to effectively distribute Cornerstone s products to all areas.

**Risks Relating to Cornerstone s Financial Results**

***Cornerstone may need additional funding and may be unable to raise capital when needed, which could force it to delay, reduce or eliminate its product development or commercialization efforts.***

Cornerstone has incurred and expects to continue to incur significant development expenses in connection with its ongoing activities, particularly as it conducts clinical trials for its product candidates. In addition, Cornerstone incurs significant commercialization expenses related to its currently marketed products for sales, marketing, manufacturing and distribution. Cornerstone incurred total commercialization expenses of $11.9 million, representing approximately 69% of its total operating expenses, in 2007, and $7.1 million, representing approximately 50% of its total operating expenses, in 2006. Cornerstone expects these commercialization expenses to increase in future periods if Cornerstone is successful in obtaining FDA approval to market the SPECTRACEF line extensions and its other product candidates. Cornerstone has used, and expects to continue to use, revenue from sales of its marketed products to fund a significant portion of the development costs of its product candidates and to expand its sales and marketing infrastructure. However, Cornerstone may need substantial additional funding for these purposes and may be unable to raise capital when needed or on acceptable terms, which would force it to delay, reduce or eliminate its development programs or commercialization efforts.

As of June 30, 2008, Cornerstone had approximately $19,000 of cash and cash equivalents on hand and available borrowing capacity of $3.9 million under its $4.0 million revolving line of credit. Based on its current operating plans, Cornerstone believes that its existing cash and cash equivalents, revenue from product sales and borrowing availability under its revolving line of credit are sufficient to continue to fund its existing level of operating expenses and capital expenditure requirements as a standalone company for the foreseeable future.

Cornerstone s future capital requirements will depend on many factors, including:

- the level of product sales from its currently marketed products and any additional products that Cornerstone may market in the future;
- the scope, progress, results and costs of development activities for Cornerstone s current product candidates;
- the costs, timing and outcome of regulatory review of Cornerstone s product candidates;
- the number of, and development requirements for, additional product candidates that Cornerstone pursues;
- the costs of commercialization activities, including product marketing, sales and distribution;

the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of Cornerstone s product candidates and products;

the extent to which Cornerstone acquires or invests in products, businesses and technologies;

the extent to which Cornerstone chooses to establish collaboration, co-promotion, distribution or other similar arrangements for its marketed products and product candidates; and

Table of Contents

the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending claims related to intellectual property owned by or licensed to Cornerstone.

***The terms of any additional capital funding that Cornerstone requires may not be favorable to Cornerstone or its stockholders.***

To the extent that Cornerstone s capital resources are insufficient to meet its future capital requirements, Cornerstone will need to finance its cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all. Cornerstone s only committed external source of funds is borrowing availability under its revolving line of credit, which is personally guaranteed by Cornerstone s President and Chief Executive Officer. Cornerstone s ability to borrow under its revolving line of credit is subject to its satisfaction of specified conditions.

If Cornerstone raises additional funds by issuing equity securities, Cornerstone s stockholders will experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting Cornerstone s ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any agreements governing debt or equity financing may also contain terms, such as liquidation and other preferences, that are not favorable to Cornerstone or its stockholders. If Cornerstone raises additional funds through collaboration and licensing arrangements with third parties, Cornerstone may be required to relinquish valuable rights to its future revenue streams or product candidates or to grant licenses on terms that may not be favorable to Cornerstone.

***Cornerstone has incurred significant losses since its inception. Cornerstone may incur losses in the future and may be unable to maintain profitability.***

From inception in 2004 through 2006, Cornerstone incurred operating losses, including net losses of $305,000 in 2006 and $11.4 million in 2005. Cornerstone s net income was $2.8 million in the six months ended June 30, 2008 and $570,000 in the year ended December 31, 2007. As of June 30, 2008, Cornerstone s accumulated deficit was $10.3 million. To date, Cornerstone has financed its operations primarily with revenue from product sales and borrowings under the Carolina Note and revolving credit facilities. Cornerstone has devoted substantially all of its efforts to:

establishing a sales and marketing infrastructure;

acquiring marketed products, product candidates and related technologies;

commercializing its marketed products; and

developing its product candidates, including conducting clinical trials.

Cornerstone expects to continue to incur significant development and commercialization expenses as it:

seeks FDA approval for the SPECTRACEF line extensions;

advances the development of its other product candidates, including its methscopolamine and antihistamine combination and hydrocodone cough suppressant product candidates;

seeks regulatory approvals for its product candidates that successfully complete clinical testing; and

expands its sales force and marketing capabilities to prepare for the commercial launch of future products, subject to FDA approval.

Cornerstone also expects to incur additional expenses to add operational, financial and management information systems and personnel, including personnel to support its product development efforts.

For Cornerstone to sustain and increase its profitability, it believes that it must succeed in commercializing additional drugs with significant market potential. This will require Cornerstone to be successful in a range of challenging activities, including:

successfully completing clinical trials of its product candidates;

Table of Contents

obtaining and maintaining regulatory approval for these product candidates; and

manufacturing, marketing and selling those products for which Cornerstone may obtain regulatory approval.

Cornerstone may never succeed in these activities and may never generate revenue that is sufficient to sustain or increase profitability on a quarterly or annual basis. Cornerstone s failure to sustain and increase its profitability could impair its ability to raise capital, expand its business, diversify its product offerings or continue its operations.

***If the estimates Cornerstone makes, or the assumptions on which it relies, in preparing its financial statements prove inaccurate, its actual results may vary from those reflected in its projections.***

Cornerstone s financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of its financial statements requires Cornerstone to make estimates and judgments that affect the reported amounts of its assets, liabilities, stockholders deficit, revenues and expenses, the amounts of charges accrued by it and related disclosure of contingent assets and liabilities. Cornerstone bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. For example, at the same time Cornerstone recognizes revenues for product sales, it also records an adjustment, or decrease, to revenue for estimated chargebacks, rebates, discounts, vouchers and returns, which management determines on a product-by-product basis as its best estimate at the time of sale based on each product s historical experience adjusted to reflect known changes in the factors that impact such reserves. Actual sales allowances may exceed Cornerstone s estimates for a variety of reasons, including unanticipated competition, regulatory actions or changes in one or more of Cornerstone s contractual relationships. Cornerstone cannot assure you, therefore, that any of its estimates, or the assumptions underlying them, will be correct.

***Cornerstone s short operating history may make it difficult for you to evaluate the success of its business to date and to assess Cornerstone s future viability.***

Cornerstone has a short operating history. Cornerstone commenced active operations in 2004. Cornerstone acquired most of its currently marketed products and product candidates through two licensing transactions, one for ALLERX in February 2005 and the other for SPECTRACEF in October 2006, after these products were already being marketed by other companies. Except for SPECTRACEF 400 mg, for which the FDA approved Cornerstone s sNDA in July 2008, Cornerstone has not received approval from the FDA for any of its products or demonstrated its ability to obtain regulatory approval for any drugs that it has developed or is developing. In addition, Cornerstone has not demonstrated its ability to initiate sales and marketing activities for successful commercialization of a newly approved product. As a relatively new business, Cornerstone may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

***Cornerstone s operating results are likely to fluctuate from period to period.***

Cornerstone anticipates that there may be fluctuations in its future operating results. Potential causes of future fluctuations in Cornerstone s operating results may include:

new product launches, which could increase revenues but also increase sales and marketing expenses;

acquisition activity;

one-time charges, such as for inventory expiration or product quality issues;

increases in research and development expenses resulting from the acquisition of a product candidate that requires significant additional development;

changes in the competitive, regulatory or reimbursement environment, which could decrease revenues or increase sales and marketing, product development or compliance costs;

unexpected product liability or intellectual property claims and lawsuits;

significant payments, such as milestones, required under collaboration, licensing and development agreements before the related product candidate has received FDA approval;

marketing exclusivity, if any, which may be obtained on certain new products;

Table of Contents

the dependence on a small number of products for a significant portion of net revenues and net income; and

price erosion and customer consolidation.

**Risks Relating to Employee Matters and Managing Growth**

***If Cornerstone fails to attract and retain key personnel, or to retain its executive management team, it may be unable to successfully develop or commercialize its products.***

Recruiting and retaining highly qualified scientific, technical and managerial personnel and research partners will be critical to Cornerstone s success. Any expansion into areas and activities requiring additional expertise, such as clinical trials, governmental approvals, contract manufacturing and sales and marketing, will place additional requirements on Cornerstone s management, operational and financial resources. These demands may require Cornerstone to hire additional personnel and will require its existing management personnel to develop additional expertise. Cornerstone faces intense competition for personnel. The failure to attract and retain personnel or to develop such expertise could delay or halt the development, regulatory approval and commercialization of its product candidates. If Cornerstone experiences difficulties in hiring and retaining personnel in key positions, it could suffer from delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect operating results. Cornerstone also experiences competition for the hiring of scientific personnel from universities and research institutions. In addition, Cornerstone relies on consultants and advisors, including scientific and clinical advisors, to assist it in formulating its development and commercialization strategy. Cornerstone s consultants and advisors may be employed by third parties and may have commitments under consulting or advisory contracts with third parties that may limit their availability to Cornerstone.

Cornerstone depends to a great extent on the principal members of its management and scientific staff. The loss of the services of any of its key personnel, in particular, Craig Collard, President and Chief Executive Officer, and Brian Dickson, M.D., Chief Medical Officer, might significantly delay or prevent the achievement of Cornerstone s development and commercialization objectives and could cause Cornerstone to incur additional costs to recruit replacements. Each member of Cornerstone s executive management team may terminate his or her employment at any time. Cornerstone does not maintain key person life insurance with respect to any of its executives. Furthermore, if Cornerstone decides to recruit new executive personnel, Cornerstone will incur additional costs.

**Risks Related to the Combined Company**

In determining whether you should approve the issuance of shares of Critical Therapeutics common stock pursuant to the merger, you should carefully read the following risk factors. Critical Therapeutics and Cornerstone anticipate that, immediately following the merger, the business of the combined company will be the respective businesses conducted by Critical Therapeutics and Cornerstone immediately prior to the merger. As a result, the risk factors section of this proxy statement/prospectus entitled Risk Factors Relating to Critical Therapeutics and Risk Factors Relating to Cornerstone together with the following risk factors, are the most significant you will face if the merger is completed.

***The integration of Critical Therapeutics and Cornerstone will be complex, time-consuming and expensive, and may ultimately be unsuccessful.***

Although Critical Therapeutics and Cornerstone both focus on development and commercialization of pharmaceutical products, their businesses are different in some material respects. Critical Therapeutics business has included substantial reliance on its only marketed products, ZYFLO and ZYFLO CR, and early stage research and development efforts related to novel compounds. On the other hand, Cornerstone s business focuses on the pursuit of opportunities

with respect to approved products or known compounds that can generally be developed more quickly and at less expense. If the merger is consummated, Cornerstone plans to close the Critical Therapeutics facility in Lexington, Massachusetts and transfer its assets and business to

Table of Contents

Cornerstone s offices in Cary, North Carolina. The integration of the Critical Therapeutics and Cornerstone businesses will be complex, time-consuming and expensive and may disrupt the combined company s business. The combined company will need to overcome significant challenges in order to realize any benefits or synergies from the merger. These challenges include the timely, efficient and successful execution of a number of post-merger events, including:

- integrating the operations and technologies of the two companies; and
- retaining strategic business partners of each company and attracting new strategic business partners.

Cornerstone expects that the combined company will incur significant costs integrating Cornerstone s and Critical Therapeutics operations, products and personnel. These may include costs associated with:

- employee redeployment, relocation or severance;
- conversion of information systems;
- combining development, regulatory, manufacturing and commercial teams and processes;
- reorganization of facilities; and
- relocation or disposition of excess equipment.

While it is currently unknown how much time will be required to integrate Cornerstone and Critical Therapeutics, some integration activities may take longer than one year. Neither Critical Therapeutics nor Cornerstone has received any notifications from third parties of their intention to terminate a material agreement or defer or delay a decision as a result of the merger. If a third party did terminate a material agreement or defer or delay a decision as a result of the merger, any such termination, deferral or delay could have a material adverse effect on the combined company s results of operations and financial condition.

***If the combined company does not successfully integrate Critical Therapeutics and Cornerstone s business operations following the consummation of the merger, the anticipated benefits of the merger may not be fully realized or may not occur for an extended period of time.***

If the combined company is unable to successfully integrate the two companies business operations following the consummation of the merger, the following could occur:

- the combined company s ongoing business could be disrupted and its management could be distracted;
- the combined company s financial and managerial controls and reporting systems and procedures could be strained;
- the combined company could experience unanticipated expenses and potential delays related to integration of the operations, technology and other resources of the two companies;
- the combined company s relationships with employees, suppliers and customers as a result of any integration of new management personnel could be impaired;
- the combined company could experience greater than anticipated costs and expenses related to restructuring, including employee severance or relocation costs and costs related to vacating leased facilities; and

potential unknown or currently unquantifiable liabilities associated with the merger and the combined operations could occur.

The combined company may not succeed in addressing these risks or any other problems encountered in connection with the merger. The inability to successfully integrate the operations, technology and personnel of Critical Therapeutics and Cornerstone, or any significant delay in achieving integration, could have a material

Table of Contents

adverse effect on the combined company after the merger and, as a result, on the market price of the combined company s common stock.

***The combined company s stock price may be volatile, and the market price of its common stock may drop following the merger.***

The market price of the combined company s common stock could be subject to significant fluctuations following the merger. Some of the factors that may cause the market price of the combined company s common stock to fluctuate include, but are not limited to:

- the results of the combined company s current and any future clinical trials;
- the results of ongoing preclinical studies and planned clinical trials of the combined company s preclinical product candidates;
- the entry into, or termination of, key agreements, including key strategic alliance agreements;
- the results and timing of regulatory reviews relating to the approval of the combined company s product candidates;
- the initiation of, material developments in or conclusion of litigation to enforce or defend any of the combined company s intellectual property rights;
- failure of any of the combined company s product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect the combined company s research and development expenditures;
- the results of clinical trials conducted by others on products that would compete with the combined company s product candidates;
- issues in manufacturing the combined company s product candidates or any approved products;
- the loss of key employees;
- the introduction of technological innovations or new commercial products by competitors of the combined company;
- changes in estimates or recommendations by securities analysts, if any, who cover the combined company s common stock;
- future sales of the combined company s common stock;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in the combined company s financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading

price of the combined company s common stock.

In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the combined company s financial condition, results of operations and reputation.

Table of Contents

***Insiders will have substantial control over the combined company and could delay or prevent a change in corporate control, including a transaction in which the combined company s stockholders could sell or exchange their shares for a premium.***

As of September 15, 2008, Cornerstone s directors, executive officers and 10% or greater stockholders, together with their affiliates, to Cornerstone s knowledge, beneficially owned, in the aggregate, approximately 71% of Cornerstone s outstanding common stock, without giving effect to shares of Cornerstone s outstanding common stock issuable to Carolina Pharmaceuticals upon the exchange or conversion of principal or interest amounts under the Carolina Note into shares of Cornerstone s common stock prior to the effective time of the merger pursuant to a noteholder agreement between Carolina Pharmaceuticals and Critical Therapeutics. Assuming that the merger occurred on this date, these persons would beneficially own, in the aggregate, approximately 51% of the outstanding common stock of the combined company, including any shares of the common stock of the combined company issuable in the merger in exchange for shares of Cornerstone s outstanding common stock to be issued to Carolina Pharmaceuticals upon the exchange or conversion of principal or interest amounts under the Carolina Note into shares of Cornerstone s common stock prior to the effective time of the merger pursuant to the noteholder agreement between Carolina Pharmaceuticals and Critical Therapeutics. As a result, Cornerstone s directors, executive officers and 10% or greater stockholders, together with their affiliates, if acting together, may have the ability to affect the outcome of matters submitted to the combined company s stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of its assets. In addition, these persons, acting together, may have the ability to control the combined company s management and affairs. Accordingly, this concentration of ownership may harm the value of the combined company s common stock by:

delaying, deferring or preventing a change in control;

impeding a merger, consolidation, takeover or other business combination; or

discouraging a potential acquirer from making an acquisition proposal or otherwise attempting to obtain control.

***The combined company s management will be required to devote substantial time to comply with public company regulations.***

As a public company, the combined company will incur significant legal, accounting and other expenses that Cornerstone did not incur as a private company, although Critical Therapeutics has been incurring such costs since its initial public offering. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and NASDAQ, impose various requirements on public companies, including with respect to corporate governance practices. The combined company s management and other personnel do not have substantial experience complying with the requirements applicable to public companies and will need to devote a substantial amount of time to these requirements. Moreover, these rules and regulations will increase the combined company s legal and financial compliance costs relative to those of Cornerstone and will make some activities more time-consuming and costly.

In addition, the Sarbanes-Oxley Act requires, among other things, that the combined company s management maintain adequate disclosure controls and procedures and internal control over financial reporting. In particular, the combined company must perform system and process evaluation and testing of its internal control over financial reporting to allow management and, as applicable, the combined company s independent registered public accounting firm to report on the effectiveness of its internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The combined company s compliance with Section 404 will require it to incur substantial accounting and related expenses and expend significant management efforts. The combined company will need to hire additional accounting and financial staff to satisfy the ongoing requirements of Section 404. Moreover, if the

combined company is not able to comply with the requirements of Section 404, or if the combined company or its independent registered public accounting firm identifies deficiencies in its internal control over financial reporting that are deemed to be material weaknesses, the combined company s financial reporting could be unreliable and misinformation could be disseminated to the

Table of Contents

public. Any failure to develop or maintain effective internal control over financial reporting or difficulties encountered in implementing or improving the combined company s internal control over financial reporting could harm the combined company s operating results and prevent it from meeting its reporting obligations. Ineffective internal controls also could cause the combined company s stockholders and potential investors to lose confidence in its reported financial information, which would likely have a negative effect on the trading price of the combined company s common stock. In addition, investors relying upon this misinformation could make an uninformed investment decision, and the combined company could be subject to sanctions or investigations by the SEC, NASDAQ or other regulatory authorities.

***The combined company may incur losses for the foreseeable future, and might never achieve profitability.***

Critical Therapeutics has experienced significant operating losses in each year since its inception in 2000, and Cornerstone experienced operating losses from its inception in 2004 and has only been profitable beginning in 2007. The combined company may never become profitable, even if the combined company is able to commercialize additional products. The combined company will need to conduct significant development, testing and regulatory compliance activities that, together with projected general and administrative expenses, which may result in substantial operating losses. Even if the combined company does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis.

***Anti-takeover provisions in the combined company s charter documents and under Delaware law could prevent or frustrate attempts by the combined company s stockholders to change the combined company s management or board of directors and hinder efforts by a third party to acquire a controlling interest in the combined company.***

The combined company will be incorporated in Delaware. Anti-takeover provisions of Delaware law and the combined company s charter documents may make a change in control more difficult, even if the stockholders desire a change in control. For example, anti-takeover provisions to which the combined company will be subject include provisions in the combined company s bylaws and certificate of incorporation providing that, except as otherwise required by law, special meetings of the stockholders may be called only by the combined company s chairman of the board of directors, the chief executive officer, the president (if the president is different than the chief executive officer) or the board of directors and that stockholders may not take action by written consent and provisions in the combined company s bylaws providing for the classification of the combined company s board of directors.

Additionally, the combined company s board of directors will have the authority to issue up to 5,000,000 shares of preferred stock and to determine the terms of those shares of stock without any further action by the combined company s stockholders. The rights of holders of the combined company s common stock are subject to the rights of the holders of any preferred stock that the combined company issues. As a result, the combined company s issuance of preferred stock could cause the market value of the combined company s common stock to decline and could make it more difficult for a third party to acquire a majority of the combined company s outstanding voting stock.

Delaware law also prohibits a corporation from engaging in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. The combined company s board of directors may use this provision to prevent changes in the combined company s management. Also, under applicable Delaware law, the combined company s board of directors may adopt additional anti-takeover measures in the future.

Table of Contents

## FORWARD-LOOKING STATEMENTS

This proxy statement/prospectus includes forward-looking statements of Critical Therapeutics within the meaning of Section 21E of the Exchange Act, which is applicable to Critical Therapeutics, but not Cornerstone, because Critical Therapeutics, unlike Cornerstone, is a public company subject to the reporting requirements of the Exchange Act. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding the proposed merger with Cornerstone, including the expected timetable for completing the transaction; future financial and operating results, including targeted product milestones; benefits and synergies of the transaction; future opportunities of the combined company; future sales and marketing efforts for currently marketed products; possible therapeutic benefits and market acceptance of currently marketed products or product candidates; the progress and timing of product development programs and related trials; the potential efficacy of product candidates; and the strategy, projected costs, prospects, plans and objectives of management, may be forward-looking statements under the provisions of The Private Securities Litigation Reform Act of 1995. In this proxy statement/prospectus, words such as anticipate, believe, could, estimate, expect, intend, may, plan, project, should, target, words that convey uncertainty of future events or outcomes are used to identify these forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including critical accounting estimates and risks relating to: the ability to consummate the proposed merger; the ability to successfully market and sell currently marketed products and product candidates, including the success of co-promotion arrangements; the ability to transition Critical Therapeutics management team effectively; the ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize currently marketed products; patient, physician and third-party payor acceptance of currently marketed products as safe and effective therapeutic products; adverse side effects experienced by patients; the heavy dependence on the commercial success of a small number of currently marketed products; the ability to maintain regulatory approvals to market currently marketed products; the ability to successfully enter into additional strategic co-promotion, collaboration or licensing transactions on favorable terms, if at all; the ability to maintain compliance with NASDAQ listing standards; conducting clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to products under development and whether such results will be indicative of results obtained in later clinical trials; the ability to obtain the substantial additional funding required to conduct development and commercialization activities; Critical Therapeutics dependence on its strategic collaboration with MedImmune; and the ability to obtain, maintain and enforce patent and other intellectual property protection for currently marketed products and product candidates. These and other risks are described in greater detail in the section entitled Risk Factors beginning on page 24 of this proxy statement/prospectus. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, any forward-looking statements in this proxy statement/prospectus represent Critical Therapeutics views only as of the date of this proxy statement/prospectus and should not be relied upon as representing Critical Therapeutics views as of any subsequent date. Critical Therapeutics anticipates that subsequent events and developments will cause its views to change. However, while Critical Therapeutics may elect to update these forward-looking statements publicly at some point in the future, Critical Therapeutics specifically disclaims any obligation to do so, except as may be required by law, whether as a result of new information, future events or otherwise. Critical Therapeutics forward-looking statements generally do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments it may make. In particular, unless otherwise stated or the context otherwise requires, Critical Therapeutics has prepared this proxy statement/prospectus as if it were going to remain an independent, standalone company. If Critical Therapeutics consummates the merger with Cornerstone, the descriptions of its strategy, future operations and financial position, future revenues, projected costs and prospects and the plans and objectives of management in this proxy statement/prospectus may no longer be applicable.

91

Table of Contents

## THE SPECIAL MEETING OF CRITICAL THERAPEUTICS STOCKHOLDERS

### Date, Time and Place

The special meeting of Critical Therapeutics stockholders will be held at 10:00 a.m., local time, on October 31, 2008, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, located at 60 State Street, Boston, Massachusetts 02109. Critical Therapeutics is sending this proxy statement/prospectus to its stockholders in connection with the solicitation of proxies by Critical Therapeutics board of directors for use at the special meeting and any adjournments or postponements of the special meeting. This proxy statement/prospectus is first being furnished to Critical Therapeutics stockholders on or about , 2008.

### Purposes of the Special Meeting

The purposes of the special meeting are to consider and act upon the following matters:

1. To approve the issuance of Critical Therapeutics common stock pursuant to the Agreement and Plan of Merger, dated as of May 1, 2008, by and among Critical Therapeutics, a wholly owned subsidiary of Critical Therapeutics, and Cornerstone, as described in this proxy statement/prospectus. A copy of the merger agreement is attached as *Annex A* to this proxy statement/prospectus.

2. To approve an amendment to Critical Therapeutics certificate of incorporation to provide for a reverse stock split of Critical Therapeutics common stock, as described in this proxy statement/prospectus. A copy of the proposed amendment is attached as *Annex B* to this proxy statement/prospectus.

3. To approve an amendment to Critical Therapeutics certificate of incorporation to change the name of Critical Therapeutics to Cornerstone Therapeutics Inc., as described in this proxy statement/prospectus. A copy of the proposed amendment is attached as *Annex C* to this proxy statement/prospectus.

4. To consider and vote upon an adjournment of the special meeting, if necessary, if a quorum is present, to solicit additional proxies if there are not sufficient votes in favor of Proposals 1, 2 and 3.

Stockholders will also consider and act on any other matters as may properly come before the special meeting or any adjournment or postponement thereof.

### Recommendation of Critical Therapeutics Board of Directors

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS HAS DETERMINED AND BELIEVES THAT THE ISSUANCE OF SHARES OF CRITICAL THERAPEUTICS COMMON STOCK IN THE MERGER, AS DESCRIBED IN THIS PROXY STATEMENT/PROSPECTUS, IS ADVISABLE, FAIR TO AND IN THE BEST INTERESTS OF CRITICAL THERAPEUTICS AND ITS STOCKHOLDERS AND HAS UNANIMOUSLY APPROVED SUCH PROPOSAL. CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 1 TO APPROVE THE ISSUANCE OF SHARES OF CRITICAL THERAPEUTICS COMMON STOCK IN THE MERGER.**

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS HAS DETERMINED AND BELIEVES THAT THE AMENDMENT TO CRITICAL THERAPEUTICS CERTIFICATE OF INCORPORATION TO EFFECT**

**THE REVERSE STOCK SPLIT, AS DESCRIBED IN THIS PROXY STATEMENT/PROSPECTUS, IS ADVISABLE, FAIR TO AND IN THE BEST INTERESTS OF CRITICAL THERAPEUTICS AND ITS STOCKHOLDERS AND HAS UNANIMOUSLY APPROVED SUCH PROPOSAL. CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 2 TO AMEND CRITICAL THERAPEUTICS CERTIFICATE OF INCORPORATION TO EFFECT THE REVERSE STOCK SPLIT.**

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS HAS DETERMINED AND BELIEVES THAT THE AMENDMENT TO CRITICAL THERAPEUTICS CERTIFICATE OF INCORPORATION**

Table of Contents

**TO CHANGE ITS NAME TO CORNERSTONE THERAPEUTICS INC. IS ADVISABLE, FAIR TO AND IN THE BEST INTERESTS OF CRITICAL THERAPEUTICS AND ITS STOCKHOLDERS AND HAS UNANIMOUSLY APPROVED SUCH PROPOSAL. CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 3 TO APPROVE THE NAME CHANGE.**

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS HAS DETERMINED AND BELIEVES THAT ADJOURNING THE SPECIAL MEETING, IF NECESSARY, IF A QUORUM IS PRESENT, TO SOLICIT ADDITIONAL PROXIES IF THERE ARE NOT SUFFICIENT VOTES IN FAVOR OF PROPOSALS 1, 2 AND 3 IS ADVISABLE, FAIR TO AND IN THE BEST INTERESTS OF CRITICAL THERAPEUTICS AND ITS STOCKHOLDERS AND HAS UNANIMOUSLY APPROVED SUCH PROPOSAL. CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 4 TO ADJOURN THE SPECIAL MEETING, IF NECESSARY, IF A QUORUM IS PRESENT, TO SOLICIT ADDITIONAL PROXIES IF THERE ARE NOT SUFFICIENT VOTES IN FAVOR OF PROPOSALS 1, 2 AND 3.**

**Record Date and Voting Power**

Only holders of record of Critical Therapeutics common stock at the close of business on the record date, September 29, 2008, are entitled to notice of, and to vote at, the special meeting. There were approximately holders of record of Critical Therapeutics common stock at the close of business on the record date. Because many of such shares are held by banks, brokers and other nominees on behalf of stockholders, Critical Therapeutics is unable to estimate the total number of stockholders represented by these record holders. At the close of business on the record date, shares of Critical Therapeutics common stock were issued and outstanding. Each share of Critical Therapeutics common stock issued and outstanding on the record date entitles the holder thereof to one vote on each matter submitted for stockholder approval. See Principal Stockholders of Critical Therapeutics beginning on page 344 of this proxy statement/prospectus for information regarding persons known to the management of Critical Therapeutics to be the beneficial owners of more than 5% of the outstanding shares of Critical Therapeutics common stock.

**Voting and Revocation of Proxies**

The proxy accompanying this proxy statement/prospectus is solicited on behalf of Critical Therapeutics board of directors for use at the special meeting.

If you are a stockholder of record of Critical Therapeutics as of the record date referred to above, you may vote in person at the special meeting or vote by proxy over the Internet, by telephone or using the enclosed proxy card. Whether or not you plan to attend the special meeting, Critical Therapeutics urges you to vote by proxy to ensure your vote is counted. You may still attend the special meeting and vote in person if you have already voted by proxy.

If your shares are registered directly in your name, you may vote:

**Over the Internet.** Go to the web site of Critical Therapeutics tabulator, BNY Mellon Shareowner Services, at http://www.proxyvoting.com/crtx and follow the instructions you will find there. You must specify how you want your shares voted or your Internet vote cannot be completed and you will receive an error message. Your shares will be voted according to your instructions.

**By Telephone.** Call (866) 540-5760 toll-free from the United States or Canada and follow the instructions. You must specify how you want your shares voted and confirm your vote at the end of the call or your

telephone vote cannot be completed. Your shares will be voted according to your instructions.

**By Mail.** Complete, date and sign the enclosed proxy card and mail it in the enclosed postage-paid envelope to BNY Mellon Shareowner Services. Your proxy will be voted according to your instructions.

Table of Contents

If you do not specify how you want your shares voted, they will be voted as recommended by Critical Therapeutics board of directors.

**In Person at the Meeting.** If you attend the meeting, you may deliver your completed proxy card in person or you may vote by completing a ballot, which will be available at the meeting.

If your shares are held in street name for your account by a bank broker or other nominee, you may vote:

**Over the Internet or By Telephone.** You will receive instructions from your broker or other nominee if you are permitted to vote over the Internet or by telephone.

**By Mail.** You will receive instructions from your broker or other nominee explaining how to vote your shares.

**In Person at the Meeting.** Contact the broker or other nominee that holds your shares to obtain a broker s proxy card and bring it with you to the meeting. **A broker s proxy is *not* the form of proxy enclosed with this proxy statement. You will not be able to vote shares you hold in street name at the meeting unless you have a proxy from your broker issued in your name giving you the right to vote the shares.**

All properly executed proxies that are not revoked will be voted at the special meeting and at any adjournments or postponements of the special meeting in accordance with the instructions contained in the proxy. If a holder of Critical Therapeutics common stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted FOR Proposal 1 to approve the issuance of shares of Critical Therapeutics common stock in the merger; FOR Proposal 2 to approve an amendment to Critical Therapeutics certificate of incorporation to effect the reverse stock split described in this proxy statement/prospectus; FOR Proposal 3 to approve an amendment to Critical Therapeutics certificate of incorporation to change the name of Critical Therapeutics to Cornerstone Therapeutics Inc. ; and FOR Proposal 4 to adjourn the special meeting, if necessary, if a quorum is present, to solicit additional proxies if there are not sufficient votes in favor of Proposals 1, 2 and 3 in accordance with the recommendation of Critical Therapeutics board of directors.

Any Critical Therapeutics stockholder of record voting by proxy, other than those stockholders who have executed a voting agreement and irrevocable proxy, has the right to revoke the proxy at any time before the polls close at the special meeting by sending a written notice stating that it would like to revoke its proxy to the Secretary of Critical Therapeutics, by voting again over the Internet or by telephone, by providing a duly executed proxy card bearing a later date than the proxy being revoked or by attending the special meeting and voting in person. Attendance alone at the special meeting will not revoke a proxy. A beneficial owner of Critical Therapeutics common stock that holds shares in street name must follow directions received from the bank, broker or other nominee that holds the shares to change its voting instructions.

**Quorum and Required Vote**

The presence, in person or represented by proxy, at the special meeting of the holders of a majority of the shares of Critical Therapeutics common stock outstanding and entitled to vote at the special meeting is necessary to constitute a quorum at the meeting. If Critical Therapeutics stockholders do not vote by proxy or in person at the special meeting, the shares of common stock of such Critical Therapeutics stockholders will not be counted as present for the purpose of determining a quorum. If a quorum is not present at the special meeting, Critical Therapeutics expects that the special meeting will be adjourned or postponed to solicit additional proxies. Abstentions and broker non-votes will be counted as present for purposes of determining the existence of a quorum. A broker non-vote occurs when a broker is not permitted to vote because the broker does not have specific voting instructions from the beneficial owner of the shares.

A description of the vote required to approve each proposal being submitted to a vote of the Critical Therapeutics stockholders is included with the description of each proposal beginning on page 152. For proposals requiring the approval of holders of a majority of the outstanding shares of Critical Therapeutics common stock, a failure to vote by proxy or in person at the special meeting, or an abstention, vote withheld

Table of Contents

or broker non-vote for such proposals, will have the same effect as a vote against the approval of such proposals. For proposals requiring the approval of a majority of the shares of Critical Therapeutics common stock present in person or represented by proxy and voting on such matter at the special meeting, a failure to submit a proxy card or vote at the special meeting, or an abstention, vote withheld or broker non-votes will have no effect on the outcome of such proposals.

**Solicitation of Proxies**

In addition to solicitation by mail, the directors, officers, employees and agents of Critical Therapeutics may solicit proxies from Critical Therapeutics stockholders by telephone, other electronic means or in person. Directors, officers, employees and agents of Critical Therapeutics will not receive any additional compensation for their services, but Critical Therapeutics will reimburse them for their out-of-pocket expenses. Critical Therapeutics also will make arrangements with banks, brokers, nominees, custodians and fiduciaries who are record holders of Critical Therapeutics common stock for the forwarding of solicitation materials to the beneficial owners of Critical Therapeutics common stock. Critical Therapeutics will reimburse these banks, brokers, nominees, custodians and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials and in obtaining voting instructions from these owners.

Critical Therapeutics has retained Morrow & Co., LLC, a proxy solicitation firm, to assist in the solicitation of proxies by mail, telephone or other electronic means or in person for a fee of approximately $5,500, plus disbursements and a fee for each completed call.

**Other Matters**

As of the date of this proxy statement/prospectus, Critical Therapeutics board of directors does not know of any business to be presented at the special meeting other than as set forth in the notice accompanying this proxy statement/prospectus. If any other matters should properly come before the special meeting, or at any adjournment or postponement of the special meeting, it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the persons voting the proxies.

Table of Contents

## THE MERGER

*This section and the section entitled The Merger Agreement beginning on page 137 of this proxy statement/prospectus describe the material aspects of the merger, including the merger agreement. While Critical Therapeutics believes that this description covers the material terms of the merger and the merger agreement, it may not contain all of the information that is important to you. You should read carefully this entire proxy statement/prospectus, including the merger agreement, which is attached as Annex A to this proxy statement/prospectus, and the other documents to which Critical Therapeutics has referred to or incorporated by reference herein. For a more detailed description of where you can find those other documents, please see the section entitled Where You Can Find More Information beginning on page 352 of this proxy statement/prospectus.*

### Background of the Merger

***Critical Therapeutics Background of the Merger***

Critical Therapeutics has regularly evaluated different strategies for improving its competitive position and enhancing stockholder value. As part of these evaluations, Critical Therapeutics has, from time to time, considered various potential strategic alternatives to pursuing its business plan, including acquisitions, divestitures, collaborations, business combinations and other strategic transactions.

In May 2006, Critical Therapeutics board of directors and management began exploring methods by which to improve Critical Therapeutics strategic position in the industry and enhance stockholder value. In September 2006, Critical Therapeutics engaged Lazard to assist in this process. As part of this September 2006 engagement, Critical Therapeutics retained Lazard as its sole financial advisor in connection with a potential strategic transaction, such as a merger, as well in connection with a potential alternative transaction, such as a business development transaction, licensing or joint venture transaction. In addition, Critical Therapeutics agreed to appoint Lazard or its affiliate as a lead-manager or lead-placement agent in connection with a public or private financing. Pursuant to this September 2006 engagement, Critical Therapeutics instructed Lazard to act within the scope of the engagement letter generally and specifically instructed Lazard to commence its search in identifying potential counterparties to both a potential strategic transaction as well as to a potential alternative transaction.

During the remainder of 2006 and early 2007, Critical Therapeutics management, with the assistance of Lazard, assessed Critical Therapeutics long-term prospects, market position and possible strategic alternatives, including a merger or similar strategic transaction. During the period between September 2006 and March 2007, Critical Therapeutics, directly or through Lazard, contacted a total of 82 companies to assess whether those companies would be interested in discussing a possible merger or similar strategic transaction with Critical Therapeutics. As a result of the foregoing contacts, preliminary discussions were held with 12 companies concerning a possible merger or similar strategic transaction.

By March 2007, none of the companies that were contacted as part of this strategic process were interested in pursuing a merger or similar strategic transaction at that time. Accordingly, Critical Therapeutics decided to remain independent and to enter into a co-promotion agreement with DEY for ZYFLO and ZYFLO CR.

Following the decision to enter into the co-promotion agreement with DEY, Critical Therapeutics secured FDA approval for ZYFLO CR in May 2007 and commercially launched the product in September 2007 with 42 sales representatives. During this time, sales of ZYFLO remained relatively flat until the launch of ZYFLO CR despite the commencement of co-promotional detailing by DEY in May 2007 with an additional 200 sales representatives. From

March 2007 through September 2007, Critical Therapeutics continued to consider other potential strategic transactions.

At a regularly scheduled board meeting on September 10, 2007, Critical Therapeutics board of directors and management reviewed the status of Critical Therapeutics commercial and research and development activities, including the risks and benefits of its upcoming launch of ZYFLO CR, as well as its financial position, long-term prospects, financing options and ongoing strategic and business development opportunities. Members of Critical Therapeutics management reviewed the status of ongoing discussions with potential strategic partners as well as other business development opportunities.

Table of Contents

At a regularly scheduled board meeting on October 4, 2007, Critical Therapeutics board of directors and management reviewed Critical Therapeutics strategy, discussed potential options for increasing stockholder value and reviewed the status of ongoing discussions with potential strategic partners. Critical Therapeutics board noted that most of Critical Therapeutics competitors were significantly larger companies, with more resources, more product offerings and larger sales forces. Critical Therapeutics board was concerned that, notwithstanding the recent commercial launch of ZYFLO CR, the company would need to create a larger set of resources, including products and pipeline, to create a sustainable business model for long-term success as an independent, standalone company. Critical Therapeutics board concluded that, given, among other things, the overall difficulty for life sciences companies to obtain financing, there were significant risks to Critical Therapeutics long-term success as an independent, standalone company and that stockholders interests would be best served if Critical Therapeutics began to explore opportunities for a range of potential strategic transactions. On October 5, 2007, Critical Therapeutics board of directors further discussed the possible benefit of exploring various strategic alternatives with the assistance of a financial advisor. Based upon Lazard s existing knowledge of Critical Therapeutics, as well as Lazard s reputation, background and experience in the industry and in mergers and acquisitions generally, Critical Therapeutics board once again formally engaged Lazard, effective October 12, 2007, to advise it in considering potential strategic alternatives. As part of this October 2007 engagement, Critical Therapeutics retained Lazard as its primary investment banker in connection with potential strategic transactions, such as a merger or acquisition transaction. Pursuant to this October 2007 engagement, Critical Therapeutics instructed Lazard to act within the scope of the engagement letter generally and specifically instructed Lazard to commence its search in identifying potential counterparties to a potential merger or acquisition. In contrast to its September 2006 engagement, Critical Therapeutics did not appoint Lazard as a financial advisor in connection with a potential licensing or business development transaction or in connection with a public or private financing.

In October 2007, Critical Therapeutics began making and receiving general inquiries to gauge interest in potential business combinations with companies seeking to gain access to a commercial-stage respiratory therapeutics business in the United States. Critical Therapeutics management and board of directors, with the assistance of Lazard, identified public and private companies that might fit Critical Therapeutics strategic plans, focusing on specialty pharmaceutical companies potentially interested in acquiring Critical Therapeutics commercial assets, as well as research and development companies with clinical-stage assets in selected therapeutic areas potentially interested in merging with Critical Therapeutics.

On November 8, 2007, Critical Therapeutics publicly announced that it was evaluating a range of strategic alternatives that could result in potential changes to its current business strategy and future operations, including the sale or divestiture of certain assets, the merger or sale of the company or other strategic transactions.

During the period between October 2007 and April 2008, Critical Therapeutics conducted a targeted process in which a total of 36 companies were contacted to assess whether those companies would be interested in discussing a possible merger, acquisition or other strategic transaction with Critical Therapeutics. In connection with these discussions, Critical Therapeutics entered into confidentiality agreements with a total of 19 companies, including Cornerstone, for the purpose of exchanging non-public information to facilitate discussions. As a result of this process, preliminary discussions were held with nine companies concerning a possible merger transaction with or acquisition of Critical Therapeutics.

Beginning in September 2007, Critical Therapeutics engaged in substantive discussions regarding a potential merger with a privately held venture-backed biotechnology company without any currently marketed products and with two product candidates in Phase II clinical development for gastrointestinal disorders, or Company X. Beginning in October 2007, Critical Therapeutics engaged in substantive discussions regarding a potential merger with a privately held venture-backed biotechnology company without any currently marketed products and with two product candidates in Phase II clinical development for respiratory diseases, or Company Y. Beginning in December 2007, Critical Therapeutics engaged in substantive discussions regarding a potential acquisition of Critical Therapeutics in a

stock-for-stock merger with a publicly traded biotechnology company with a commercial organization and several FDA-approved marketed drugs, or Company Z. Company Z had a

market capitalization during the period from December 2007 to March 2008 in the range of approximately $40 million to $200 million.

In connection with this process, Critical Therapeutics also prepared an electronic data room containing documents related to Critical Therapeutics material legal contracts, corporate records, financial information, sales and marketing materials, corporate policies and procedures, insurance information and information regarding products and product candidates, including research data, clinical trial reports, regulatory filings and correspondence and patents and patent applications. In connection with discussions regarding a possible merger or acquisition between October 2007 and May 2008, Critical Therapeutics granted access to this electronic data room to a total of eight companies, each of which had entered into a confidentiality agreement with Critical Therapeutics, including Cornerstone, Company X, Company Y and Company Z. In addition, in connection with such discussions during this period, Critical Therapeutics was granted access to the electronic data rooms of Cornerstone, Company X, Company Y and Company Z.

Critical Therapeutics conducted substantive scientific, commercial and financial due diligence on several of these companies during this period.

Throughout this period, Critical Therapeutics management apprised the board of directors of these discussions both informally and through reports at board meetings. Between October 1, 2007 and May 1, 2008, Critical Therapeutics board met 29 times and discussed the ongoing strategic alternatives review process and discussions and negotiations with companies as part of this strategic review process.

On November 20, 2007, Critical Therapeutics board of directors held a meeting, also attended by members of Critical Therapeutics management and representatives of Wilmer Cutler Pickering Hale and Dorr LLP, or WilmerHale, Critical Therapeutics outside legal counsel, Lazard and outside diligence consultants, at which the board was briefed on the ongoing process to identify possible strategic transactions. Among other matters discussed, the board was updated with respect to the potential strategic partners that Critical Therapeutics management, with the assistance of Lazard, had identified and which Lazard had contacted at the direction of Critical Therapeutics management or which had contacted Lazard in response to Critical Therapeutics public announcement that it was evaluating a range of strategic alternatives. In addition, the board received an overview of the development pipeline, commercial potential, business and operations of Company X and Company Y together with preliminary terms for a potential transaction with each company. After discussion, Critical Therapeutics board authorized management to continue discussions and engage in mutual due diligence with both companies, while continuing efforts to identify additional potential strategic partners.

At meetings on December 11 and 12, 2007, Critical Therapeutics board of directors received an update on the status of Critical Therapeutics strategic process from management and Lazard. Management and Critical Therapeutics outside diligence consultants reviewed with the board scientific, commercial and financial information on Company X and Company Y.

In late December 2007, after a number of meetings and discussions between Critical Therapeutics and Company X regarding the acquisition process and participating in a significant mutual due diligence review process, Company X indicated that it had other business priorities and had decided not to move forward with a merger with Critical Therapeutics. At the point discussions with Company X ended, Company X had preliminarily proposed a transaction in which Critical Therapeutics stockholders would hold approximately 35% of the combined company.

In January 2008, after discussions between Critical Therapeutics and Company Y regarding the acquisition process, participating in a significant mutual due diligence review process and conducting negotiations regarding a definitive agreement, Company Y indicated that it had other business priorities and had decided not to move forward with a merger with Critical Therapeutics. At the point discussions with Company Y ended, Company Y had preliminarily

proposed a transaction in which Critical Therapeutics stockholders would hold approximately 50% of the combined company.

During the fourth quarter of 2007 and the first quarter of 2008, sales of ZYFLO CR were lower than anticipated. In addition, in March 2008, Critical Therapeutics began to experience problems in the supply chain for ZYFLO CR. During this time, Critical Therapeutics cash position also continued to decrease. In

addition, conditions in the national economy and the financial markets in particular continued to present challenges for life sciences companies seeking financing. These factors reinforced the view of Critical Therapeutics board of directors that concluding the strategic alternatives process as soon as practical was in the best interests of Critical Therapeutics stockholders.

On February 14, 2008, Critical Therapeutics board of directors held a meeting, also attended by members of Critical Therapeutics management and representatives of WilmerHale and Lazard, at which the board received an update on the strategic process, including information regarding the commercial, clinical and business operations of Company Z.

On February 15, 2008, Craig Collard, President, Chief Executive Officer and a director of Cornerstone, contacted by telephone Frank E. Thomas, then President, Chief Executive Officer and a director of Critical Therapeutics, to discuss the possibility of a strategic transaction between Cornerstone and Critical Therapeutics.

On February 20, 2008, Critical Therapeutics and Cornerstone executed a confidentiality agreement for the purpose of exchanging non-public information to facilitate discussions between the two companies. On or after February 20, 2008, Critical Therapeutics sent a detailed presentation regarding Critical Therapeutics via e-mail to representatives of Cornerstone.

On February 28, 2008, Thomas P. Kelly, Chief Financial Officer and Senior Vice President of Finance and Corporate Development of Critical Therapeutics, and Roger Heerman, Vice President of Sales and Marketing of Critical Therapeutics, held a telephone conference with Mr. Collard and Brian Dickson, M.D., Chief Medical Officer of Cornerstone. During this telephone conference, the parties made presentations to each other regarding their respective companies and their businesses.

On March 3, 2008, Cornerstone sent a detailed presentation regarding Cornerstone via e-mail to representatives of Critical Therapeutics and Lazard. Also on March 3, 2008, Mr. Collard e-mailed Mr. Thomas to inform him that Cornerstone was interested in continuing discussions regarding a transaction with Critical Therapeutics.

On March 4, 2008, Critical Therapeutics publicly announced that Mr. Thomas had informed Critical Therapeutics board of directors that he had resigned as a director effective March 2, 2008 and was resigning as President and Chief Executive Officer effective March 31, 2008, and that Trevor Phillips, Ph.D., Critical Therapeutics Senior Vice President of Operations and Chief Operating Officer, had been appointed as a director effective March 4, 2008 and would become President and Chief Executive Officer of Critical Therapeutics effective April 1, 2008.

In early March 2008, after many meetings and discussions between Critical Therapeutics and Company Z regarding the acquisition process, participating in a significant mutual due diligence review process and conducting negotiations regarding a definitive agreement, Company Z indicated that it had other business priorities and had decided not to move forward with a merger with Critical Therapeutics. At the point discussions with Company Z ended, Company Z had preliminarily proposed a transaction in which Critical Therapeutics stockholders would receive Company Z common stock with an aggregate market value of approximately $65 million. Shortly after discontinuing merger discussions in March 2008, Company Z experienced significant regulatory setbacks with the FDA and a significant reduction in its market capitalization.

On March 7, 2008, Mr. Collard, Dr. Dickson and Alastair McEwan, Chairman of the board of directors of Cornerstone, traveled to Critical Therapeutics offices in Lexington, Massachusetts and met with Dr. Phillips, Mr. Thomas, Mr. Kelly, Mr. Heerman and Roberta Tucker, Senior Vice President of Regulatory Affairs of Critical Therapeutics. During this meeting, the managements of both Cornerstone and Critical Therapeutics made presentations regarding their respective companies and their businesses. Representatives of Jefferies & Company, Inc., or Jefferies, Cornerstone s financial advisor, were also present at this meeting.

Following the meeting on March 7, 2008, Critical Therapeutics and Cornerstone continued mutual due diligence on the business, assets and liabilities of each company, including telephone conferences and review

of information contained in each company s electronic dataroom. In addition, representatives of both companies management teams and their respective legal and financial advisors conducted numerous discussions regarding the potential terms of a transaction.

On March 12, 2008, Dr. Phillips, Mr. Kelly, Mr. Heerman and Mr. Thomas held a telephone conference call with Mr. Collard, Mr. McEwan and a representative of Jefferies regarding the proposed transaction with Cornerstone and the acquisition process in general.

On March 13, 2008, representatives of the parties management and financial advisors held a further telephone conference to discuss the proposed transaction with Cornerstone, potential deal terms and the acquisition process in general.

On March 17, 2008, Cornerstone sent a letter via e-mail to Critical Therapeutics reflecting a non-binding expression of interest regarding a potential merger with Critical Therapeutics in which Critical Therapeutics would issue common stock to Cornerstone stockholders for all of Cornerstone s equity capital. In this letter, Cornerstone preliminarily proposed a transaction in which Critical Therapeutics stockholders would hold 34% of the combined company, based on Critical Therapeutics having a cash balance at closing of at least $20 million.

Critical Therapeutics board of directors met on March 20, 2008 in Cambridge, Massachusetts and by teleconference, together with members of Critical Therapeutics management and representatives of WilmerHale and Lazard. At this meeting, representatives of Cornerstone made a presentation to Critical Therapeutics board regarding a possible strategic transaction between Cornerstone and Critical Therapeutics and related matters. Following this presentation, Cornerstone s representatives departed the meeting. Critical Therapeutics board then continued to discuss a potential strategic transaction with Cornerstone. As part of this discussion, Lazard provided an update on the status of the strategic review process, including recent conversations with potential strategic partners, and discussed with the board particular terms of Cornerstone s non-binding expression of interest and tactical perspectives with respect to a potential transaction with Cornerstone. In addition, Dr. Phillips made a presentation to the board regarding the potential transaction and members of management discussed the due diligence performed on Cornerstone and the strategy, business and prospects for a combined company. Following this discussion, Critical Therapeutics board met in executive session without Critical Therapeutics management, other than Dr. Phillips, and unanimously agreed to continue to pursue discussions with Cornerstone and directed management to report back to the board on their progress.

Following the meeting on March 20, 2008, representatives of Critical Therapeutics and Cornerstone continued their mutual due diligence.

On March 21, 2008, Critical Therapeutics sent a letter via e-mail to Cornerstone with a response to Cornerstone s expression of interest regarding potential terms of a transaction. In this letter, Critical Therapeutics preliminarily proposed a transaction in which Critical Therapeutics stockholders would hold 35% of the combined company. Critical Therapeutics also delivered to Cornerstone a detailed due diligence request list regarding legal, finance and other business matters relating to Cornerstone.

On March 25, 2008, Jefferies, on behalf of Cornerstone, sent a letter via e-mail in response to Critical Therapeutics letter of March 21, 2008. In that letter, Cornerstone preliminarily proposed a transaction in which Critical Therapeutics stockholders would hold 31% of the combined company, based on a projected cash balance at closing for Critical Therapeutics of $12 million.

On March 25, 2008, Critical Therapeutics board of directors held a meeting by telephone conference at which, among other matters, Dr. Phillips provided the board with an update regarding the potential transaction with Cornerstone as

well as the status of Critical Therapeutics discussions with and due diligence regarding other potential strategic transaction candidates.

Also on March 25, 2008, Critical Therapeutics, Cornerstone and their respective financial advisors held a telephone conference to discuss financial projections for each company, including as described in the section

of this proxy statement/prospectus entitled Financial Projections, and the possible impact that such projections for each company could have with respect to the combined company.

On March 28, 2008, members of Critical Therapeutics management attended due diligence meetings at Cornerstone s offices in Cary, North Carolina with Chenyqua Baldwin, Vice President, Finance of Cornerstone. On March 29, 2008, members of Critical Therapeutics management attended due diligence meetings in Cary, North Carolina.

Also on March 28, 2008, Cornerstone sent a letter to Critical Therapeutics clarifying particular items regarding potential deal terms, including proposing an exclusivity period and proposing that the proportion of the combined company that Critical Therapeutics stockholders would hold would be variable based on Critical Therapeutics cash balance at closing.

On March 31, 2008, Critical Therapeutics received a legal due diligence request list from Cornerstone regarding legal, finance and other business matters relating to Critical Therapeutics.

Also on March 31, 2008, Critical Therapeutics board of directors held a meeting by telephone conference. Also present at this telephonic meeting were members of Critical Therapeutics management and representatives of WilmerHale and Lazard. At this meeting, among other things, Dr. Phillips provided an update with respect to, and led a discussion with input from Lazard regarding, Critical Therapeutics ongoing process of reviewing strategic alternatives, including the status of discussions with Cornerstone and with other potential strategic transaction candidates. The discussions with these other potential strategic transaction candidates were all at an early stage without any specific economic terms proposed with respect to a potential transaction. After extensive discussions, the board determined that the company should pursue further negotiations with Cornerstone regarding a possible business combination on a non-exclusive basis.

On April 8 and 9, 2008, representatives of Cornerstone and Critical Therapeutics and representatives of Jefferies and Lazard discussed further financial projections for each company, including as described in the section of this proxy statement/prospectus entitled Financial Projections, and the possible impact that such projections for each company could have with respect to the combined company.

On April 10, 2008, Critical Therapeutics board of directors held a meeting in Cambridge, Massachusetts and by telephone conference. Also present at this meeting were members of Critical Therapeutics management and representatives of WilmerHale and Lazard, as well as Mr. Collard, Mr. McEwan and Dr. Dickson of Cornerstone and representatives of Jefferies. During the meeting, Cornerstone s representatives made presentations to Critical Therapeutics board regarding a possible strategic transaction between Critical Therapeutics and Cornerstone. Following these presentations, Cornerstone s representatives departed the meeting. Critical Therapeutics board then continued to discuss a potential strategic transaction with Cornerstone. Following this discussion, Dr. Phillips updated Critical Therapeutics board regarding the status of discussions with other potential strategic transaction candidates, all of which were at an early stage without any specific economic terms proposed with respect to a potential transaction. Critical Therapeutics board determined that the stage of discussions with Cornerstone justified additional mutual due diligence and the negotiation of definitive documentation regarding a merger between the two companies.

On April 14, 2008, Critical Therapeutics board of directors met by telephone conference. Mr. Kelly and Scott B. Townsend, Senior Vice President of Legal Affairs, General Counsel and Secretary of Critical Therapeutics, participated in the meeting. Dr. Phillips and Mr. Kelly provided the board with an update on the status of discussions with Cornerstone regarding a potential transaction, the status of a draft definitive merger agreement with Cornerstone and the status of financial and accounting due diligence on Cornerstone. Dr. Phillips then provided Critical Therapeutics board with an update regarding the status of discussions with other potential candidates for a strategic transaction.

On April 15, 2008, Critical Therapeutics provided Cornerstone with a first draft of a definitive merger agreement. Between April 15, 2008 and April 30, 2008, representatives of Critical Therapeutics and Cornerstone negotiated the terms of the proposed merger agreement. Negotiations focused on, among other matters, the conditions to closing, post-signing operating covenants, termination rights, the amount of

termination fees, required levels of cash, debt and working capital, representations and warranties, and the timing of the re-audit of Cornerstone s financial statements.

On April 18, 2008, Dr. Phillips and Mr. Collard met by telephone conference to discuss various aspects of the proposed transaction, including operational and business strategy issues.

On April 24, 2008, Critical Therapeutics board of directors held a meeting by telephone conference. Also present at this meeting were members of Critical Therapeutics management and representatives of WilmerHale and Lazard. At this meeting, among other things, Dr. Phillips provided an update on and led a discussion regarding the potential transaction with Cornerstone, including the status of financial, tax and accounting due diligence, and the status of negotiations regarding a draft definitive agreement with Cornerstone. After discussion, the board determined to proceed with the final negotiations of a definitive agreement with Cornerstone.

Following Critical Therapeutics board meeting on April 24, 2008, representatives of Critical Therapeutics, WilmerHale, Lazard, Cornerstone, Jefferies and Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., or Smith Anderson, Cornerstone s outside legal counsel, continued negotiation of the definitive agreement. Preliminary agreement was reached on a number of matters, including agreement that the exchange ratio in the merger would provide that Critical Therapeutics stockholders would hold 30% of the combined company but without a requirement that Critical Therapeutics have a minimum amount of cash or working capital as a closing condition and without any potential adjustment to the exchange ratio based on Critical Therapeutics amount of cash or working capital at closing. Later on April 24, 2008, WilmerHale provided a revised draft of the merger agreement to Cornerstone and its advisors reflecting these discussions and the preliminary agreement of Critical Therapeutics and Cornerstone.

On April 26, 2008, Critical Therapeutics board of directors held a meeting by telephone conference to receive an update on due diligence matters with respect to Cornerstone and the strategic fit of Critical Therapeutics and Cornerstone.

Between April 25, 2008 and April 30, 2008, counsel for Critical Therapeutics and Cornerstone had various communications regarding the merger agreement and related acquisition agreements and exchanged revised drafts of these agreements.

On April 28, 2008, members of Critical Therapeutics management and WilmerHale met by telephone conference with representatives of Cornerstone, including Mr. Collard, and Smith Anderson to discuss the process for final approval and execution of a definitive merger agreement, related disclosure obligations under applicable securities laws and regulations and a proposed communications plan and timeline.

On April 30, 2008, Critical Therapeutics board of directors met to further consider the proposed merger of Critical Therapeutics with Cornerstone and related matters. Also participating in the meeting were members of Critical Therapeutics management and representatives of WilmerHale and Lazard. During that meeting:

- Dr. Phillips provided a summary of Critical Therapeutics process to date regarding consideration of a proposed transaction with Cornerstone, including an overview of the strategic alternatives process undertaken by the board generally, discussions with Cornerstone s management, negotiations with respect to a proposed merger agreement and due diligence conducted by Critical Therapeutics;

- Dr. Phillips discussed with the board the strategic business rationale for a combination with Cornerstone, including with respect to the marketed products of, and product candidates under development by, both Critical Therapeutics and Cornerstone and the ability of the combined company to utilize Cornerstone s existing commercial organization;

Dr. Phillips presented his views on the competitive environment facing Critical Therapeutics;

the board discussed Critical Therapeutics prospects as an independent, standalone company;

Mr. Kelly reviewed with the board various financial modeling scenarios, including models for Critical Therapeutics as a standalone company, Cornerstone as a standalone company and a combination of

Table of Contents

Critical Therapeutics and Cornerstone, in each case utilizing different assumptions regarding future business plans and financing needs;

Mr. Heerman and Ms. Tucker discussed with the board their due diligence review with respect to Cornerstone s historical and projected sales, its sales and marketing organization and its regulatory affairs;

Lazard discussed with the board financial aspects of the proposed merger, including, among other things, a summary of the results of Critical Therapeutics strategic review process and Lazard s preliminary views with respect to the exchange ratio provided for in the proposed merger in preparation for Critical Therapeutics board meeting to be held on May 1, 2008;

the WilmerHale representatives outlined the fiduciary duties and responsibilities of the board under applicable law and summarized the principal terms of the proposed merger agreement and related acquisition agreements; and

the board discussed at length the proposed business combination with Cornerstone, the appropriateness of the exchange ratio in the proposed merger and the nature of the deal protections, closing conditions, covenants and termination rights set forth in the proposed merger agreement, the competitive environment facing Critical Therapeutics and Critical Therapeutics prospects as an independent, standalone company.

Critical Therapeutics board of directors then reconvened on May 1, 2008 with members of Critical Therapeutics management and representatives of Critical Therapeutics legal and financial advisors. During that meeting:

Critical Therapeutics board of directors again engaged in a discussion regarding the matters discussed at the April 30, 2008 meeting relating to the proposed business combination between Critical Therapeutics and Cornerstone;

Lazard reviewed with Critical Therapeutics board its financial analysis of the exchange ratio provided for in the merger and rendered to Critical Therapeutics board an oral opinion, which opinion was confirmed by delivery of a written opinion, dated May 1, 2008, to the effect that, as of that date and based upon and subject to the assumptions, factors and qualifications set forth in its opinion, the exchange ratio was fair, from a financial point of view, to Critical Therapeutics; and

Critical Therapeutics board further discussed and deliberated at length the proposed business combination with Cornerstone, the appropriateness of the exchange ratio in the proposed merger and the nature of the deal protections, closing conditions, covenants and termination rights set forth in the proposed merger agreement, the competitive environment facing Critical Therapeutics and Critical Therapeutics prospects as an independent, standalone company.

Following this discussion and deliberation, Critical Therapeutics board of directors unanimously determined that the merger agreement and the transactions contemplated thereby, including the merger, are advisable, fair to and in the best interests of the stockholders of Critical Therapeutics, unanimously approved the merger agreement and unanimously recommended that the Critical Therapeutics stockholders approve the issuance of Critical Therapeutics common stock pursuant to the merger agreement, the reverse stock split of Critical Therapeutics common stock and the name change of Critical Therapeutics to Cornerstone Therapeutics Inc.

Critical Therapeutics and Cornerstone executed the merger agreement on May 1, 2008 after the close of trading on The NASDAQ Global Market and made a joint public announcement of the proposed transaction later that day.

***Cornerstone s Background of the Merger***

A key element of Cornerstone s strategy to achieve its goal of becoming a leading specialty pharmaceutical company is to expand its product portfolio through the acquisition of rights to FDA-approved respiratory pharmaceutical products with well-established safety and efficacy profiles and projected annual sales providing

attractive returns on investment. In furtherance of this strategic element, Cornerstone s management continually monitors developments in other pharmaceutical companies with a respiratory focus or respiratory products for acquisition opportunities.

Following Critical Therapeutics public announcement on November 8, 2007 that it was evaluating a range of strategic alternatives, including the sale or divestiture of certain assets, the merger or sale of the company or other strategic transactions, Cornerstone management began reviewing Critical Therapeutics filings with the SEC to assess whether Critical Therapeutics or one of its products might be a possible acquisition candidate for Cornerstone.

Between February 15, 2008 and March 3, 2008, Craig Collard, President, Chief Executive Officer and a director of Cornerstone, Alastair McEwan, Chairman of the board of directors of Cornerstone, and Brian Dickson, M.D., Cornerstone s Chief Medical Officer, engaged in preliminary e-mail and telephonic communications and exchanged non-public information with management of Critical Therapeutics to learn about each other s respective companies and businesses and to preliminarily determine whether a transaction between Cornerstone and Critical Therapeutics might provide a good strategic fit. On March 3, 2008, Mr. Collard e-mailed Frank E. Thomas, then President and Chief Executive Officer of Critical Therapeutics, to inform him that Cornerstone was interested in continuing discussions regarding a transaction with Critical Therapeutics, and Mr. McEwan requested a meeting with David Price, a managing director of Jefferies, to solicit Jefferies assistance in connection with a possible transaction with Critical Therapeutics. Thereafter, throughout the negotiation process with Critical Therapeutics, Mr. Collard and Mr. McEwan, both of whom are Cornerstone employees and who comprised the entire board of directors of Cornerstone throughout the period of negotiations, served as the principal negotiators for the transaction on behalf of Cornerstone. Because of this direct and personal involvement in negotiating the terms and conditions of the merger, Mr. Collard and Mr. McEwan, who were the only directors of Cornerstone throughout the period, did not formally convene as a board of directors to consider the potential terms of a transaction and the acquisition process in general and instead collaborated closely on the transaction on a daily basis until they acted to formally approve the transaction on May 1, 2008 through the adoption of board resolutions.

On March 5, 2008, Mr. Price traveled to Cornerstone s headquarters in Cary, North Carolina, to discuss the engagement of Jefferies as exclusive financial advisor to Cornerstone in connection with a possible transaction with Critical Therapeutics. Mr. Collard and Mr. McEwan, constituting all of the directors of Cornerstone, agreed to tentatively engage Jefferies, and Jefferies agreed to immediately commence providing advice and assistance to Cornerstone, in each case, subject to the execution of a mutually satisfactory engagement agreement. Following the March 5, 2008 meeting until the execution of the merger agreement, Mr. Collard and Mr. McEwan received active and continual support from Mr. Price of Jefferies, who accompanied Mr. Collard and Mr. McEwan to each of their negotiating meetings with Critical Therapeutics management.

On March 7, 2008, Mr. Collard, Dr. Dickson and Mr. McEwan for Cornerstone, Critical Therapeutics senior management, including Dr. Phillips, Mr. Thomas and Mr. Kelly, and Jefferies representatives, including Mr. Price, participated in meetings in Lexington, Massachusetts during which Critical Therapeutics and Cornerstone management teams made presentations regarding their respective companies and their businesses. Following these meetings, during the period from March 7 to March 17, 2008, each company engaged in extensive due diligence on the business, assets and liabilities of the other company, and representatives of both companies management teams and their respective legal and financial advisors conducted numerous discussions regarding the potential terms of a transaction and the acquisition process in general.

On March 17, 2008, Cornerstone sent a letter via e-mail to Critical Therapeutics reflecting a non-binding expression of interest regarding a potential merger with Critical Therapeutics in which Critical Therapeutics would issue common stock to Cornerstone stockholders for all of Cornerstone s equity capital. In this letter, Cornerstone preliminarily proposed a transaction in which Critical Therapeutics stockholders would hold 34% of the combined company, based

on Critical Therapeutics having a cash balance at closing of at least $20 million.

On March 19, 2008, Jefferies provided to Mr. Collard and Mr. McEwan its perspectives regarding negotiating tactics with respect to a potential transaction with Critical Therapeutics. Following a presentation by

Table of Contents

representatives of Cornerstone on March 20, 2008 to Critical Therapeutics board regarding a possible strategic transaction between Cornerstone and Critical Therapeutics and related matters, on March 21, 2008, Critical Therapeutics sent a letter via e-mail to Cornerstone with a response to Cornerstone s expression of interest regarding potential terms of a transaction. In this letter, Critical Therapeutics preliminarily proposed a transaction in which Critical Therapeutics stockholders would hold 35% of the combined company.

On March 25, 2008, Jefferies, on behalf of Cornerstone, sent a letter via e-mail in response to Critical Therapeutics letter of March 21, 2008. In that letter, Cornerstone preliminarily proposed a transaction in which Critical Therapeutics stockholders would hold 31% of the combined company, based on a projected cash balance at closing for Critical Therapeutics of $12 million.

Also on March 25, 2008, Critical Therapeutics, Cornerstone and their respective financial advisors held a telephone conference to discuss financial projections for each company, including as described in the section of this proxy statement/prospectus entitled Financial Projections, and the possible impact that such projections for each company could have with respect to the combined company.

On March 28, 2008, Cornerstone and Jefferies entered into a written agreement confirming Cornerstone s engagement of Jefferies as exclusive financial advisor to Cornerstone in connection with a possible transaction with Critical Therapeutics.

Also on March 28, 2008, Cornerstone sent a letter to Critical Therapeutics clarifying particular items regarding potential deal terms, including proposing an exclusivity period and proposing that the proportion of the combined company that Critical Therapeutics stockholders would hold would be variable based on Critical Therapeutics cash balance at closing.

On April 8 and 9, 2008, representatives of Cornerstone and Critical Therapeutics and representatives of Jefferies and Lazard discussed further financial projections for each company, including as described in the section of this proxy statement/prospectus entitled Financial Projections, and the possible impact that such projections for each company could have with respect to the combined company.

Following a second presentation by representatives of Cornerstone on April 10, 2008 to Critical Therapeutics board regarding a possible strategic transaction between Cornerstone and Critical Therapeutics and related matters, on April 15, 2008, Critical Therapeutics provided Cornerstone with a first draft of a definitive merger agreement. Between April 15, 2008 and April 30, 2008, representatives of Critical Therapeutics and Cornerstone negotiated the terms of the proposed merger agreement. Negotiations focused on, among other matters, the conditions to closing, post-signing operating covenants, termination rights, the amount of termination fees, required levels of cash, debt and working capital, representations and warranties, and the timing of the re-audit of Cornerstone s financial statements.

On April 24, 2008, Cornerstone representatives, including Mr. Collard, Mr. McEwan and Dr. Dickson, met in New York, New York with representatives of Critical Therapeutics, WilmerHale, Lazard, Jefferies and Smith Anderson, Cornerstone s outside legal counsel, and continued negotiation of the definitive agreement. Preliminary agreement was reached on a number of matters, including agreement that the exchange ratio in the merger would provide that Critical Therapeutics stockholders would hold 30% of the combined company but without a requirement that Critical Therapeutics have a minimum amount of cash or working capital as a closing condition and without any potential adjustment to the exchange ratio based on Critical Therapeutics amount of cash or working capital at closing.

Between April 24, 2008 and April 30, 2008, counsel for Critical Therapeutics and Cornerstone had various communications regarding the merger agreement and related acquisition agreements and exchanged revised drafts of these agreements. Throughout this period, Smith Anderson was in frequent communication with Mr. Collard and

Mr. McEwan regarding finalizing the terms and conditions of the merger agreement.

On April 28, 2008, members of Critical Therapeutics management and WilmerHale met by telephone conference with representatives of Cornerstone, including Mr. Collard, and Smith Anderson to discuss the process for final approval and execution of a definitive merger agreement, related disclosure obligations under applicable securities laws and regulations and a proposed communications plan and timeline.

Table of Contents

Following discussions with Jefferies and Smith Anderson representatives and Cornerstone management, Mr. Collard and Mr. McEwan engaged in extensive discussion and deliberation regarding the proposed business combination with Critical Therapeutics, the appropriateness of the exchange ratio in the proposed merger and the nature of the deal protections, closing conditions, covenants and termination rights set forth in the proposed merger agreement, the prospects for increasing ZYFLO CR net revenues taking into account sales force efficiencies to be achieved by promoting ZYFLO CR alongside Cornerstone s other products during calls on prescribers and prospects of the combined company.

On May 1, 2008, Cornerstone s board of directors, unanimously determined that the merger agreement and the transactions contemplated thereby, including the merger, are advisable, fair to and in the best interests of the stockholders of Cornerstone, and unanimously approved the merger agreement and the other transactions contemplated by the merger agreement, and unanimously recommended that Cornerstone s stockholders approve the merger with Critical Therapeutics.

Critical Therapeutics and Cornerstone executed the merger agreement on May 1, 2008 after the close of trading on The NASDAQ Global Market and made a joint public announcement of the proposed transaction later that day. Contemporaneously with Cornerstone s execution of the merger agreement, Cornerstone and Carolina Pharmaceuticals, which is the holder of the Carolina Note, entered into an agreement that provides, among other things, for the exchange or conversion of the outstanding principal amount of the Carolina Note into shares of Cornerstone s common stock prior to the effective time of the merger.

On May 2, 2008, holders of a majority of the shares of Cornerstone s outstanding common stock acting by written consent without a meeting in accordance with Section 228 of the Delaware General Corporation Law and Cornerstone s bylaws approved the merger agreement and the transactions contemplated thereby.

**Financial Projections**

During the course of the mutual due diligence review process undertaken in connection with the proposed merger, Critical Therapeutics and Cornerstone each made available to the other party non-public business and financial information about their companies, including financial projections.

The projections provided by Critical Therapeutics included the following estimates of Critical Therapeutics future financial performance as an independent, standalone company.

| | Projected for Critical Therapeutics | |
|---|---|---|
| | 2008 | 2009 |
| | (Unaudited, amounts in thousands) | |
| Total Revenues | $ 19,194 | $ 27,857 |
| Operating Loss | (21,477) | (12,941) |
| Net Loss | (21,114) | (12,922) |

The projections in the table above assumed, among other things, that Critical Therapeutics would not reduce its workforce, that a sufficient supply of ZYFLO CR would remain available for sale and that there would be no significant alterations or terminations of material contractual relationships.

The projections provided by Cornerstone included the following estimates of Cornerstone s future financial performance as an independent, standalone company.

| | Projected for Cornerstone | |
|---|---|---|
| | 2008 | 2009 |
| | (Unaudited, amounts in thousands) | |
| Total Revenues | $ 48,957 | $ 92,953 |
| Operating Income | 7,880 | 21,763 |
| Net Income | 3,922 | 12,524 |

The projections in the table above assumed, among other things, that clinical testing and regulatory milestones with respect to Cornerstone s product candidates would be achieved at costs and on timetables substantially consistent with management s expectations, that a sufficient supply of all of Cornerstone s currently marketed

Table of Contents

products and products targeted for launch during 2008 or 2009 would remain available for sale and that Cornerstone would experience no significant alterations or terminations of material contractual relationships.

The non-public business and financial information and projections that Critical Therapeutics and Cornerstone provided to each other during the course of the mutual due diligence review process were provided solely in connection with such due diligence review and not expressly for inclusion or incorporation by reference in any filing with the SEC or document to be provided to stockholders of either company. The estimates of future financial performance for Critical Therapeutics and Cornerstone described above also were provided to Lazard for use in its financial analysis in connection with its opinion. There is no guarantee that any projections will be realized, or that the assumptions on which they are based will prove to be correct.

Critical Therapeutics does not as a matter of course make public any projections as to future performance or earnings, other than limited guidance for periods no longer than one year. As a private company, Cornerstone has not previously made available to the public any projections as to its future financial performance. The projections set forth above are included in this proxy statement/prospectus only because this information was provided to the other party. The projections were not prepared with a view to public disclosure or compliance with the published guidelines of the SEC or the guidelines established by the American Institute of Certified Public Accountants regarding projections or forecasts. The projections do not purport to present operations in accordance with GAAP.

Neither Critical Therapeutics nor Cornerstone s independent auditors, nor any other independent accountants, have compiled, examined or performed any procedures with respect to the prospective financial information contained herein, nor have they expressed any opinion or any other form of assurance on such information or its achievability, and assume no responsibility for, and disclaim any association with, the prospective financial information.

Each company s internal financial forecasts, upon which the projections were based in part, are, in general, prepared solely for internal use, such as budgeting and other management decisions, and are subjective in many respects. As a result, these internal financial forecasts are susceptible to interpretations and periodic revision based on actual experience and business developments. The projections reflect numerous assumptions made by the management of Critical Therapeutics and Cornerstone, as applicable, and general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond the company s control. Accordingly, there can be no assurance that the assumptions made in preparing the projections will prove accurate or that any of the projections will be realized.

Differences between actual and projected results are to be expected, and actual results may be materially greater or less than those contained in the projections due to numerous risks and uncertainties, including but not limited to the important factors listed in the section of this proxy statement/prospectus entitled Risk Factors. All projections are forward-looking statements, and these and other forward-looking statements are expressly qualified in their entirety by the risks and uncertainties identified in the Risk Factors section.

The inclusion of the projections herein should not be regarded as an indication that any of Critical Therapeutics, Cornerstone, Lazard or their respective affiliates or representatives considered or consider the projections to be a prediction of actual future events, and the projections should not be relied upon as such. Except as may be required by law, none of Critical Therapeutics, Cornerstone, or any of their respective affiliates or representatives intends to update or otherwise revise the projections to reflect circumstances existing or arising after the date such projections were generated or to reflect the occurrence of future events, even in the event that any or all of the assumptions underlying the projections are shown to be in error.

**Stockholders are cautioned not to place undue reliance on the projections included in this proxy statement/prospectus.**

107

Table of Contents

**Reasons for the Merger**

***Mutual Reasons for the Merger***

Critical Therapeutics and Cornerstone believe that the combined company resulting from the merger will have the following potential advantages:

The combined company will be a larger respiratory-focused specialty pharmaceutical company with multiple approved products, a more balanced revenue stream and important product development opportunities.

The combined company is expected to focus its resources on developing a successful specialty pharmaceutical business without the additional challenge of trying to simultaneously build an early-stage drug development pipeline.

There are significant potential synergies and cost savings that Critical Therapeutics and Cornerstone believe can be achieved by consolidating the infrastructures of the two companies and allowing management to fully leverage the combined sales force across multiple revenue generating products.

***Critical Therapeutics Reasons for the Merger***

In evaluating the merger, Critical Therapeutics board of directors consulted with senior management and Critical Therapeutics legal and financial advisors, and, in the course of reaching its determination to approve the merger agreement, Critical Therapeutics board of directors considered a number of factors, including the following:

historical and current information concerning Critical Therapeutics business, including negative trends in its financial performance, financial condition, operations and competitive position;

current financial market conditions, and historical market prices, volatility and trading information with respect to Critical Therapeutics common stock;

Critical Therapeutics limited prospects if it were to remain an independent, standalone company as a result of factors such as slower than anticipated sales of ZYFLO CR, ongoing supply chain issues relating to ZYFLO CR, Critical Therapeutics declining cash balance, the expenses and fixed costs associated with its operations and prospects for development and commercialization of additional products, particularly given Critical Therapeutics limited resources;

substantial doubt regarding the ability of Critical Therapeutics to continue as a going concern without obtaining additional financing and the view of Critical Therapeutics board of directors regarding Critical Therapeutics ability to secure additional financing as an independent, standalone company;

historical and current information concerning Cornerstone s business, financial performance, financial condition, operations and management, including the results of a due diligence investigation of Cornerstone conducted by Critical Therapeutics management and advisors;

the view that the combination with Cornerstone would result in a combined company with the potential for enhanced future growth and value as compared to Critical Therapeutics as an independent, standalone company;

the opportunity for Critical Therapeutics stockholders to participate in the potential future value of the combined company;

Critical Therapeutics board of directors view as to the potential for other third parties to enter into strategic relationships with or acquire Critical Therapeutics on favorable terms, if at all, based on the lack of interest expressed by third parties during the strategic alternatives review process undertaken by Critical Therapeutics;

the belief that the merger was more favorable to Critical Therapeutics stockholders than any other alternative reasonably available to Critical Therapeutics and its stockholders, including the alternative of remaining an independent, standalone company;

Table of Contents

the opinion of Lazard, dated May 1, 2008, to Critical Therapeutics board of directors as to the fairness, from a financial point of view and as of the date of the opinion, to Critical Therapeutics of the exchange ratio provided for in the merger, as more fully described below under the caption Opinion of Critical Therapeutics Financial Advisor; and

the terms and conditions of the merger agreement, including:

the determination that the relative percentage ownership of the combined company by Critical Therapeutics stockholders and Cornerstone s stockholders is consistent with Critical Therapeutics perceived valuations of each company at the time Critical Therapeutics board of directors approved the merger agreement;

the non-solicitation provisions limiting Cornerstone s ability to engage in discussions or negotiations regarding, or furnish to any person any information with respect to, assist or participate in any effort or attempt by any person with respect to, or otherwise cooperate in any way with, an alternative acquisition proposal;

Critical Therapeutics rights under the merger agreement to pursue alternative acquisition proposals received independently under specified circumstances;

the conditions to the closing of the merger and the likelihood of their being satisfied, including the requirement that Cornerstone s stockholders adopt the merger agreement by written consents in lieu of a meeting promptly following the signing of the merger agreement;

the absence of any condition to the closing of the merger requiring Critical Therapeutics to have a minimum amount of cash or working capital at closing and the absence of any terms providing for an adjustment to the exchange ratio based on the amount of cash or working capital at closing for Critical Therapeutics;

the requirement that holders of a majority of the shares of Cornerstone s outstanding common stock enter into agreements providing that the stockholders vote in favor of adoption of the merger agreement and against any proposal made in opposition to, or in any competition with, the merger;

Critical Therapeutics board of directors belief that the $1.0 million termination fee payable to Cornerstone in the circumstances set forth in the merger agreement was reasonable in the context of termination fees that were payable in other comparable transactions and would not be likely to preclude another party from making a superior acquisition proposal; and

the qualification of the merger as a reorganization for U.S. federal income tax purposes, with the result that in the merger neither Critical Therapeutics nor Cornerstone s stockholders will recognize gain or loss for U.S. federal income tax purposes.

In the course of its deliberations, Critical Therapeutics board of directors also considered a variety of risks and other countervailing factors related to entering into the merger agreement, including the following:

the risk that the merger might not be completed in a timely manner or at all due to failure to satisfy the closing conditions, some of which are outside of Critical Therapeutics control;

if the merger is not completed, the potential adverse effect of the public announcement of the merger on Critical Therapeutics business, including its significant supplier, distributor and other key business relationships, Critical Therapeutics ability to attract and retain key personnel and Critical Therapeutics overall competitive position;

the immediate and substantial dilution of the equity interests and voting power of Critical Therapeutics stockholders upon completion of the merger;

the ability of Cornerstone s current stockholders to significantly influence the combined company s business after the completion of the merger;

Table of Contents

the risk that the combined company may be unable to raise needed additional capital in the near term and that such additional capital, even if available, will be further dilutive to Critical Therapeutics stockholders and may be at a lower valuation than reflected in the merger;

the restrictions that the merger agreement imposes on soliciting competing acquisition proposals;

the fact that Critical Therapeutics would be obligated to pay the $1.0 million termination fee to Cornerstone if the merger agreement is terminated under the following circumstances:

- by Cornerstone because the merger has not occurred by November 30, 2008 due to the failure of Critical Therapeutics to satisfy closing conditions relating to approval by Critical Therapeutics stockholders of the proposals to be presented at the special meeting, the fulfillment of Critical Therapeutics obligations under the merger agreement or delivery of the stockholder agreements entered into with Critical Therapeutics stockholders;

- by Cornerstone or Critical Therapeutics because Critical Therapeutics stockholders fail to approve the proposals presented at the special meeting if at or prior to the time of such failure an acquisition proposal relating to Critical Therapeutics was announced and was not abandoned or withdrawn;

- by Cornerstone because (i) Critical Therapeutics board of directors fails to make, withdraws or modifies its recommendation that Critical Therapeutics stockholders vote for the proposals presented at the special meeting, (ii) after the receipt by Critical Therapeutics of an acquisition proposal, Critical Therapeutics board of directors fails to reconfirm its recommendation of the merger agreement or the merger, (iii) Critical Therapeutics board of directors approves or recommends any acquisition proposal, (iv) a tender or exchange offer for Critical Therapeutics common stock is commenced (other than by Cornerstone or its affiliates) and Critical Therapeutics board of directors recommends that Critical Therapeutics stockholders tender their shares in such offer or fails to recommend against acceptance of such offer, (v) Critical Therapeutics breaches its non-solicitation obligations or stockholder covenants or (vi) Critical Therapeutics fails to hold the special meeting by November 28, 2008; or

- by Cornerstone because there has been a breach of or failure to perform any representation, warranty, covenant or agreement by Critical Therapeutics that would cause conditions to the closing of the merger not to be satisfied, and such failure or breach is not cured within 30 days after receipt of written notice from Cornerstone, provided that such 30 day period may not extend beyond November 26, 2008;

Critical Therapeutics inability to terminate the merger agreement if it accepts or recommends a superior acquisition proposal;

the restrictions on the conduct of Critical Therapeutics business prior to the completion of the merger, which require Critical Therapeutics to carry on its business in the usual, regular and ordinary course in substantially the same manner as previously conducted, subject to specific additional restrictions, which may delay or prevent Critical Therapeutics from pursuing business opportunities that would otherwise be in its best interests as a standalone company;

the requirement that Critical Therapeutics receive approval from NASDAQ for the re-listing of Critical Therapeutics common stock in connection with the merger based on NASDAQ s initial listing requirements;

the challenges and costs of combining administrative operations and the substantial expenses to be incurred in connection with the merger, including the risks that delays or difficulties in completing the administrative integration and such other expenses, as well as the additional public company expenses and obligations that Cornerstone will be subject to in connection with the merger that it has not previously been subject to, could adversely affect the combined company s operating results and preclude the achievement of some benefits anticipated from the merger;

Table of Contents

the possible volatility, at least in the short term, of the trading price of Critical Therapeutics common stock resulting from the announcement and pendency of the merger;

the possible earlier than anticipated loss of key management or other personnel of Critical Therapeutics;

the risk of diverting management s attention from day-to-day operations to implement the merger;

the interests of Critical Therapeutics executive officers and directors in the transactions contemplated by the merger agreement, as described in the section of this proxy statement/prospectus entitled Interests of Critical Therapeutics Directors and Executive Officers in the Merger ; and

various other applicable risks associated with the business of Cornerstone and the combined company and the merger, including those described in the section of this proxy statement/prospectus entitled Risk Factors.

The foregoing discussion of the factors considered by Critical Therapeutics board of directors is not intended to be exhaustive, but does set forth the principal factors considered by Critical Therapeutics board of directors. Critical Therapeutics board of directors collectively reached the unanimous conclusion to approve the merger agreement in light of the various factors described above and other factors that each member of Critical Therapeutics board of directors deemed relevant. In view of the wide variety of factors considered by the members of Critical Therapeutics board of directors in connection with their evaluation of the merger agreement and the complexity of these matters, Critical Therapeutics board of directors did not consider it practical, and did not attempt, to quantify, rank or otherwise assign relative weights to the specific factors it considered in reaching its decision. Critical Therapeutics board of directors made its decision based on the totality of information presented to and considered by it. In considering the factors discussed above, individual directors may have given different weights to different factors.

Critical Therapeutics board of directors unanimously determined that the merger agreement and the merger are advisable, fair to and in the best interests of Critical Therapeutics stockholders and unanimously approved the merger agreement. **Critical Therapeutics board of directors unanimously recommends that Critical Therapeutics stockholders approve the issuance of Critical Therapeutics common stock pursuant to the merger agreement, the reverse stock split and the change of Critical Therapeutics name to Cornerstone Therapeutics Inc.**

***Cornerstone s Reasons for the Merger***

In evaluating the merger, Cornerstone s board of directors consulted with senior management and Cornerstone s legal and financial advisors, and, in the course of reaching its determination to approve the merger agreement, Cornerstone s board of directors considered a number of factors, including the following:

historical and current information concerning Cornerstone s business, financial performance, financial condition, operations and management;

the view that the combination with Critical Therapeutics would result in a combined company with the potential for enhanced future growth and value as compared to Cornerstone as an independent, standalone company;

the likely greater range of options available to the combined company to access private and public equity markets should additional capital be needed in the future than the range of options available to Cornerstone as a private company;

the opportunity to expand Cornerstone s respiratory product portfolio with ZYFLO CR;

the possibility of other strategic alternatives to the merger for enhancing long-term stockholder value, including investigating strategic transactions with other companies;

the possibility of other alternatives to expand Cornerstone s product portfolio through the acquisition of rights to FDA-approved respiratory products through asset purchase or licensing transactions not involving a strategic combination with another company;

Table of Contents

the terms and conditions of the merger agreement, including:

- the determination that the relative percentage ownership of the combined company by Critical Therapeutics stockholders and Cornerstone s stockholders is consistent with Cornerstone s perceived valuations of each company at the time Cornerstone s board of directors approved the merger agreement;
- the non-solicitation provisions limiting both Cornerstone s and Critical Therapeutics ability to engage in discussions or negotiations regarding, or furnish to any person any information with respect to, assist or participate in any effort or attempt by any person with respect to, or otherwise cooperate in any way with, an alternative acquisition proposal;
- the conditions to the closing of the merger and the likelihood of their being satisfied, including the fact that stockholders that own in the aggregate approximately 19% of Critical Therapeutics outstanding common stock will have entered into agreements with Cornerstone that provide, among other things, that the stockholders will vote in favor of the issuance of shares of Critical Therapeutics common stock in the merger;
- the requirement that holders of a majority of the shares of Cornerstone s outstanding common stock enter into agreements providing that the stockholders vote in favor of adoption of the merger agreement and against any proposal made in opposition to, or in any competition with, the merger;
- the requirement that the principal amount outstanding under the Carolina Note be exchanged for shares of Cornerstone common stock immediately prior to the consummation of the merger such that the resulting dilution would be suffered solely by Cornerstone s current stockholders and not by Critical Therapeutics current stockholders; and
- the qualification of the merger as a reorganization for U.S. federal income tax purposes, with the result that in the merger neither Critical Therapeutics nor Cornerstone s stockholders will recognize gain or loss for U.S. federal income tax purposes.

In the course of its deliberations, Cornerstone s board of directors also considered a variety of risks and other countervailing factors related to entering into the merger agreement, including the following:

- negative trends in Critical Therapeutics financial performance, financial condition, operations and competitive position;
- current financial market conditions, and historical market prices, volatility and trading information with respect to Critical Therapeutics common stock;
- slower than anticipated sales of ZYFLO CR, ongoing supply chain issues relating to ZYFLO CR, Critical Therapeutics declining cash balance and the expenses and fixed costs associated with Critical Therapeutics operations and prospects for internal development and commercialization of additional products by Critical Therapeutics;
- the risk that the merger might not be completed in a timely manner or at all due to failure to satisfy the closing conditions, some of which are outside of Cornerstone s control, and the potential adverse effect of the public announcement of the merger on Cornerstone s reputation and ability to obtain financing in the future in the event the merger is not completed;

the immediate and substantial dilution of the equity interests and voting power of Cornerstone s stockholders upon completion of the merger;

the risk that the combined company may be unable to raise needed additional capital in the near term and that such additional capital, even if available, will be further dilutive to Cornerstone s stockholders and may be at a lower valuation than reflected in the merger;

the restrictions that the merger agreement imposes on soliciting competing acquisition proposals or pursuing alternative respiratory product acquisition opportunities that may come to Cornerstone s attention prior to completion of the merger;

Table of Contents

the restrictions on the conduct of Cornerstone s business prior to the completion of the merger, which require Cornerstone to carry on its business in the usual, regular and ordinary course in substantially the same manner as previously conducted, subject to specific additional restrictions, which may delay or prevent Cornerstone from pursuing business opportunities that would otherwise be in its best interests as a standalone company;

the risk that Critical Therapeutics might not receive approval from NASDAQ for re-listing of Critical Therapeutics common stock in connection with the merger based on NASDAQ s initial listing requirements;

the challenges and costs of combining administrative operations and the substantial expenses to be incurred in connection with the merger, including the risks that delays or difficulties in completing the administrative integration and such other expenses, as well as the additional public company expenses and obligations that Cornerstone will be subject to in connection with the merger that it has not previously been subject to, could adversely affect the combined company s operating results and preclude the achievement of some benefits anticipated from the merger;

the possible volatility, at least in the short term, of the trading price of Critical Therapeutics common stock resulting from the announcement and pendency of the merger;

the possible earlier than anticipated loss of key management or other personnel of Critical Therapeutics;

the risk of diverting management s attention from day-to-day operations to implement the merger;

the interests of Cornerstone s executive officers and directors in the transactions contemplated by the merger agreement, as described in the section of this proxy statement/prospectus entitled Interests of Cornerstone s Directors and Executive Officers in the Merger ; and

various other applicable risks associated with the business of Cornerstone and the combined company and the merger, including those described in the section of this proxy statement/prospectus entitled Risk Factors.

The foregoing discussion of the factors considered by Cornerstone s board of directors is not intended to be exhaustive, but does set forth the principal factors considered by Cornerstone s board of directors. Cornerstone s board of directors collectively reached the unanimous conclusion to approve the merger agreement in light of the various factors described above and other factors that each member of Cornerstone s board of directors deemed relevant. In view of the wide variety of factors considered by the members of Cornerstone s board of directors in connection with its evaluation of the merger agreement and the complexity of these matters, Cornerstone s board of directors did not consider it practical, and did not attempt, to quantify, rank or otherwise assign relative weights to the specific factors it considered in reaching its decision. Cornerstone s board of directors made its decision based on the totality of information presented to and considered by it. In considering the factors discussed above, individual directors may have given different weights to different factors. The Cornerstone board of directors conducted an overall analysis of the factors described above, including thorough discussions with, and questioning of, Cornerstone s management and Cornerstone s legal and financial advisors, and considered the factors overall to be favorable to, and to support, its determination.

**Opinion of Critical Therapeutics Financial Advisor**

Lazard is acting as financial advisor to Critical Therapeutics in connection with the merger. As part of that engagement, Critical Therapeutics board of directors requested that Lazard evaluate the fairness, from a financial point of view, to Critical Therapeutics of the exchange ratio provided for in the merger. At a meeting of Critical

Therapeutics board of directors held on May 1, 2008 to evaluate the merger, Lazard delivered to Critical Therapeutics board of directors an oral opinion, which opinion was confirmed by delivery of a written opinion, dated May 1, 2008, to the effect that, as of that date and based upon and subject to certain

Table of Contents

assumptions, factors and qualifications, the exchange ratio was fair, from a financial point of view, to Critical Therapeutics.

**The full text of Lazard s opinion, which sets forth, among other things, the procedures followed, assumptions made, matters considered and qualifications and limitations on the review undertaken by Lazard in connection with its opinion, is attached to this proxy statement/prospectus as *Annex D* and is incorporated into this proxy statement/prospectus by reference. The material aspects of Lazard s opinion are summarized below. Lazard s opinion was addressed to Critical Therapeutics board of directors, was only one of many factors considered by Critical Therapeutics board of directors in its evaluation of the merger and only addresses the fairness of the exchange ratio from a financial point of view to Critical Therapeutics. Lazard s opinion does not address the merits of the underlying decision by Critical Therapeutics to engage in the merger or related transactions or the relative merits of the merger or related transactions as compared to any other transaction or business strategy in which Critical Therapeutics might engage, and is not intended to, and does not, constitute a recommendation to any stockholder as to how such stockholder should vote or act with respect to the merger or any matter relating to the merger. Lazard s opinion was necessarily based on economic, monetary, market and other conditions as in effect on, and the information made available to Lazard as of, May 1, 2008, the date of its opinion. Lazard assumes no responsibility for updating or revising its opinion based on circumstances or events occurring after the date of the opinion.**

In connection with its opinion, Lazard:

- reviewed the financial terms and conditions of the merger agreement;
- analyzed certain publicly available historical business and financial information relating to Critical Therapeutics and certain historical business and financial information relating to Cornerstone;
- reviewed various financial forecasts and other data provided to Lazard by Critical Therapeutics relating to Critical Therapeutics business and financial forecasts and other data provided to Lazard by Cornerstone, as adjusted by Critical Therapeutics, relating to Cornerstone s business;
- held discussions with members of the senior managements of Critical Therapeutics and Cornerstone with respect to the businesses and prospects of Critical Therapeutics and Cornerstone, respectively;
- reviewed public information with respect to certain other companies in lines of business Lazard believed to be generally relevant in evaluating the businesses of Critical Therapeutics and Cornerstone, respectively;
- reviewed historical stock prices and trading volumes of Critical Therapeutics common stock; and
- conducted such other financial studies, analyses and investigations as Lazard deemed appropriate.

Lazard assumed and relied upon the accuracy and completeness of the foregoing information, without independent verification of such information. Lazard did not conduct any independent valuation or appraisal of any of the assets or liabilities (contingent or otherwise) of Critical Therapeutics or Cornerstone or concerning the solvency or fair value of Critical Therapeutics or Cornerstone, and Lazard was not furnished with such valuation or appraisal. With respect to the financial forecasts that Lazard reviewed (including, in the case of Cornerstone, adjustments to such forecasts by Critical Therapeutics), Lazard assumed, with Critical Therapeutics consent, that they were reasonably prepared on bases reflecting the best currently available estimates and judgments of the managements of Critical Therapeutics and Cornerstone, as the case may be, as to the future financial performance of Critical Therapeutics and Cornerstone. Lazard assumed no responsibility for and expressed no view as to such forecasts or the assumptions on which they

were based. Lazard relied on the assessments of Critical Therapeutics management as to the validity of, and risks associated with, the products and product candidates of Critical Therapeutics and Cornerstone (including, without limitation, the timing and probability of successful development, testing and marketing, and of approval by appropriate governmental authorities, of such products and product candidates). Lazard was advised by representatives of Critical Therapeutics and Cornerstone that a new audit of the historical financial statements of Cornerstone would be performed, and Lazard assumed, with Critical Therapeutics consent, that such audited historical

financial statements, when completed, would not vary materially from the audited historical financial statements of Cornerstone provided to Lazard by Cornerstone.

In rendering its opinion, Lazard assumed, with Critical Therapeutics consent, that the merger and related transactions (including, without limitation, the reverse stock split and the contemplated exchange or conversion of the Carolina Note into shares of Cornerstone common stock as a condition to the closing of the merger) would be consummated on the terms described in the merger agreement, without any waiver or modification of any material terms or conditions. Lazard also assumed, with Critical Therapeutics consent, that obtaining the necessary regulatory or third party approvals and consents for the merger or any related transaction would not have an adverse effect on Critical Therapeutics, Cornerstone or the merger. Lazard further assumed, with Critical Therapeutics consent, that the representations and warranties of Critical Therapeutics and Cornerstone contained in the merger agreement were true and complete and that the merger would qualify for U.S. federal income tax purposes as a reorganization within the meaning of Section 368(a) of the Code. Lazard did not express any opinion as to any tax or other consequences that might result from the merger or any related transaction, nor did Lazard s opinion address any legal, tax, regulatory or accounting matters, as to which Lazard understood that Critical Therapeutics obtained such advice as it deemed necessary from qualified professionals. Lazard expressed no view or opinion as to any terms or other aspects or implications of the merger (other than the exchange ratio to the extent expressly specified in its opinion) or any related transaction, including, without limitation, the form or structure of the merger, any adjustment to the exchange ratio resulting from the reverse stock split, any other aspect or implication of the reverse stock split or any agreements or arrangements entered into in connection with, or otherwise contemplated by, the merger. In addition, Lazard expressed no view or opinion as to the fairness of the amount or nature of, or any other aspects relating to, the compensation to any officers, directors or employees of any parties to the merger, or class of such persons, relative to the exchange ratio or otherwise. Further, Lazard did not express any opinion as to the price at which shares of Critical Therapeutics common stock would trade at any time subsequent to the announcement of the merger. Except as described above, Critical Therapeutics imposed no other instructions or limitations on Lazard with respect to the investigations made or the procedures followed by Lazard in rendering its opinion. The issuance of Lazard s opinion was approved by an authorized committee of Lazard.

The following is a brief summary of the material financial and comparative analyses that Lazard deemed to be appropriate for this type of transaction and that were reviewed with Critical Therapeutics board of directors by Lazard in connection with rendering its opinion. The summary of Lazard s analyses described below is not a complete description of the analyses underlying Lazard s opinion. The preparation of a financial opinion is a complex analytical process involving various determinations as to the most appropriate and relevant methods of financial analyses and the application of those methods to the particular circumstances, and, therefore, is not readily susceptible to summary description. In arriving at its opinion, Lazard considered the results of all of the analyses and did not draw, in isolation, conclusions from or with regard to any factor or analysis considered by it. Rather, Lazard made its determination as to fairness on the basis of its experience and professional judgment after considering the results of all of the analyses.

In its analyses, Lazard considered industry performance, general business, economic, market and financial conditions and other matters, many of which are beyond the control of Critical Therapeutics and Cornerstone. No company used in Lazard s analyses is identical to Cornerstone or Critical Therapeutics, and an evaluation of the results of those analyses is not entirely mathematical. Rather, the analyses involve complex considerations and judgments concerning financial and operating characteristics and other factors that could affect the public trading or other values of the companies analyzed. The estimates contained in Lazard s analyses and the ranges of valuations resulting from any particular analysis are not necessarily indicative of actual values or predictive of future results or values, which may be significantly more or less favorable than those suggested by the analyses. In addition, analyses relating to the value of businesses or securities do not purport to be appraisals or to reflect the prices at which businesses or securities actually may be sold. Accordingly, the estimates used in, and the results derived from, Lazard s analyses are inherently

subject to substantial uncertainty.

Table of Contents

The financial analyses summarized below include information presented in tabular format. **In order to fully understand Lazard s financial analyses, the tables must be read together with the text of each summary. The tables alone do not constitute a complete description of the financial analyses. Considering the data in the tables below without considering the full narrative description of the financial analyses, including the methodologies and assumptions underlying the analyses, could create a misleading or incomplete view of Lazard s financial analyses.** For purposes of the analyses summarized below, the term merger exchange ratio refers to the implied exchange ratio of 2.9946x, calculated as set forth in the merger agreement based on the product of 2.3333 multiplied by the quotient of 43,479,198 divided by the estimate of Cornerstone s management of the fully diluted shares of Cornerstone common stock as of April 30, 2008 and before adjustment for the reverse stock split of Critical Therapeutics common stock to occur in connection with the merger. For purposes of the Cornerstone Financial Analyses summarized below, the term implied per share merger consideration refers to the implied per share value of $1.86 based on a merger exchange ratio of 2.9946x and Critical Therapeutics closing stock price on April 30, 2008 of $0.62 per share.

***Cornerstone Financial Analyses***

*Discounted Cash Flow Analysis*

Lazard performed a discounted cash flow analysis of Cornerstone to calculate the estimated present value as of March 31, 2008 of the standalone unlevered, after-tax free cash flows that Cornerstone was forecasted to generate (i) from the last three quarters of calendar year 2008 through the full calendar year 2011 utilizing internal estimates of Cornerstone s management and (ii) from 2012 through the full calendar year 2015 utilizing estimates prepared by Critical Therapeutics management in consultation with Lazard, in each case as risk-adjusted by Critical Therapeutics management. Lazard calculated estimated terminal values for Cornerstone by applying a range of earnings before interest, taxes, depreciation and amortization, referred to as EBITDA, terminal value multiples of 7.5x to 9.5x to Cornerstone s calendar year 2015 estimated EBITDA. The unlevered, after-tax free cash flows and terminal values were discounted to present value as of March 31, 2008 using discount rates ranging from 14.0% to 16.0%. Given that Cornerstone would have no outstanding debt or cash as of the closing date of the merger, Cornerstone s implied enterprise value was the same as its implied equity value. Accordingly, in calculating an implied per share equity reference range for Cornerstone, the implied enterprise value range derived from the estimated terminal values was divided by the number of outstanding shares of Cornerstone s common stock. This analysis indicated the following implied per share equity reference range for Cornerstone, as compared to the implied per share merger consideration:

| Implied Per Share Equity Reference Range for Cornerstone | Implied Per Share Merger Consideration |
|---|---|
| $4.50 - $5.50 | $1.86 |

*Selected Publicly Traded Companies Analysis*

Lazard reviewed publicly available financial information for the following six publicly traded mid-stage specialty pharmaceutical companies:

| Selected Publicly Traded Company | Enterprise Value (as of April 30, 2008) |
|---|---|
| Bentley Pharmaceuticals, Inc. | $ 348,200,000 |
| K-V Pharmaceutical Company | $ 1,234,900,000 |

| | |
|---|---|
| Par Pharmaceutical Companies, Inc. | $ 498,700,000 |
| Salix Pharmaceuticals, Ltd. | $ 244,400,000 |
| Sciele Pharma, Inc. | $ 839,800,000 |
| Valeant Pharmaceuticals International | $ 1,608,400,000 |

Lazard reviewed, among other things, enterprise values of the selected companies, calculated as market value based on closing stock prices on April 30, 2008, plus debt and preferred stock, less cash and cash equivalents, as multiples of estimated revenue and estimated EBITDA for calendar years 2008, 2009 and 2010. Lazard then applied a range of selected multiples of estimated revenue for calendar years 2008, 2009 and 2010 of 1.75x to 2.5x, 1.5x to 2.0x and 1.0x to 1.5x, respectively, and estimated EBITDA for calendar years 2008,

Table of Contents

2009 and 2010 of 8.0x to 9.0x, 7.0x to 8.0x and 6.0x to 7.0x, respectively, derived from the selected companies, excluding outliers, to corresponding financial data of Cornerstone. Estimated financial data of the selected companies were based on publicly available research analysts estimates and other publicly available information. Estimated financial data of Cornerstone were based on internal estimates of Cornerstone s management, as adjusted by Critical Therapeutics management. This analysis indicated the following implied per share equity reference range for Cornerstone based on the financial metrics referred to above after applying a discount of 15% (which discount was applied to take into account, among other things, the illiquidity of Cornerstone s stock due to the fact that, unlike the selected publicly traded companies, Cornerstone is not publicly traded), as compared to the implied per share merger consideration:

| Implied Per Share Equity Reference Range for Cornerstone | Implied Per Share Merger Consideration |
|---|---|
| $3.10 - $4.05 | $1.86 |

***Critical Therapeutics Financial Analyses***

*Discounted Cash Flow Analysis*

Lazard performed a sum-of-the-parts discounted cash flow analysis of Critical Therapeutics to calculate the estimated present value as of March 31, 2008 of the standalone unlevered, after-tax free cash flows that Critical Therapeutics product, ZYFLO CR, and product candidates, zileuton injection, alpha-7 and HMGB1, were forecasted to generate from the last three quarters of calendar year 2008 through the full calendar year 2015 in the case of Critical Therapeutics ZYFLO CR product and through the full calendar year 2020 in the case of Critical Therapeutics product candidates. Estimated financial data of Critical Therapeutics were based on internal estimates of Critical Therapeutics management with respect to Critical Therapeutics product and product candidates, probability-weighted, in the case of estimated financial results attributable to a product candidate, to reflect management s assessments as to the likelihood of obtaining regulatory approval to commercialize the product candidate. Lazard calculated estimated terminal values for Critical Therapeutics by applying perpetuity growth rates of (10.0%) to (0.0%) to the estimated unlevered, after-tax free cash flow attributable in calendar year 2015 to Critical Therapeutics ZYFLO CR product and to the estimated unlevered, after-tax free cash flows attributable in calendar year 2020 to Critical Therapeutics product candidates. The unlevered, after-tax free cash flows and terminal values were discounted to present value as of March 31, 2008 using discount rates ranging from 15.0% to 17.0%. In calculating an implied per share equity reference range for Critical Therapeutics, the implied enterprise value range for Critical Therapeutics derived from the estimated terminal values was adjusted for Critical Therapeutics net cash (no debt adjustment was made given that Critical Therapeutics had no outstanding debt) and such adjusted amount was then divided by the number of outstanding shares of Critical Therapeutics common stock. This analysis indicated the following implied per share equity reference range for Critical Therapeutics, as compared to the per share closing price of Critical Therapeutics common stock on April 30, 2008:

| Implied Per Share Equity Reference Range for Critical Therapeutics | Per Share Closing Price of Critical Therapeutics Common Stock |
|---|---|
| $1.20 - $1.95 | $0.62 |

Table of Contents

*Selected Publicly Traded Companies Analysis*

Lazard reviewed publicly available financial information for the following 10 publicly traded emerging specialty pharmaceutical companies:

| Selected Publicly Traded Company | | Enterprise Value (as of April 30, 2008) |
|---|---|---|
| Barrier Therapeutics, Inc. | $ | 41,100,000 |
| Eurand N.V. | $ | 724,400,000 |
| Indevus Pharmaceuticals, Inc. | $ | 372,200,000 |
| Inspire Pharmaceuticals, Inc. | $ | 185,400,000 |
| ISTA Pharmaceuticals, Inc. | $ | 73,100,000 |
| Jazz Pharmaceuticals, Inc. | $ | 198,000,000 |
| Noven Pharmaceuticals, Inc. | $ | 167,000,000 |
| POZEN Inc. | $ | 331,800,000 |
| Santarus, Inc. | $ | 72,800,000 |
| Sucampo Pharmaceuticals, Inc. | $ | 515,400,000 |

Lazard reviewed, among other things, enterprise values of the selected companies as a multiple of estimated revenue for calendar years 2008, 2009 and 2010. Lazard then applied a range of selected multiples of estimated revenue for calendar years 2008, 2009 and 2010 of 1.5x to 2.25x, 1.0x to 1.5x and 0.75x to 1.25x, respectively, derived from the selected companies to corresponding financial data of Critical Therapeutics. Estimated financial data of the selected companies were based on publicly available research analysts estimates and other publicly available information. Estimated financial data of Critical Therapeutics were based on internal estimates of Critical Therapeutics s management with respect to Critical Therapeutics product and product candidates, probability-weighted, in the case of estimated financial results attributable to a product candidate, to reflect management s assessments as to the likelihood of obtaining regulatory approval to commercialize the product candidate. This analysis indicated the following implied per share equity reference range for Critical Therapeutics based on the financial metrics referred to above, as compared to the per share closing price of Critical Therapeutics common stock on April 30, 2008:

| Implied Per Share Equity Reference Range for Critical Therapeutics | Per Share Closing Price of Critical Therapeutics Common Stock |
|---|---|
| $1.20 - $1.55 | $0.62 |

***Implied Pro Forma Ownership Analyses***

Using the implied equity reference ranges for Cornerstone and Critical Therapeutics derived from the Discounted Cash Flow Analysis and Selected Publicly Traded Companies Analysis described above, Lazard derived an implied equity ownership percentage for Cornerstone s stockholders in the combined company upon consummation of the merger. This analysis indicated the following range of implied pro forma equity ownership percentages for Cornerstone s stockholders, as compared to the pro forma equity ownership percentage for Cornerstone s stockholders implied by the merger exchange ratio:

**Cornerstone Implied Pro Forma Equity Ownership**

| Percentage Reference Ranges | | |
|---|---|---|
| **Discounted Cash Flow Analysis** | **Selected Publicly Traded Companies Analysis** | **Cornerstone Pro Forma Equity Ownership Percentage Implied by Merger Exchange Ratio** |
| 64% - 77% | 60% - 73% | 70.0% |

***Miscellaneous***

In connection with Lazard s services as Critical Therapeutics financial advisor, Critical Therapeutics has agreed to pay to Lazard an aggregate fee of approximately $1.25 million, a portion of which was payable upon the rendering of Lazard s opinion and approximately $1.0 million of which is contingent upon the closing of the merger. Critical Therapeutics also has agreed to reimburse Lazard for its reasonable expenses,

Table of Contents

including reasonable attorneys fees, and to indemnify Lazard and certain related parties against certain liabilities that may arise out of the rendering of its advice, including certain liabilities under U.S. federal securities laws.

Lazard, as part of its investment banking business, is continually engaged in the valuation of businesses and their securities in connection with mergers and acquisitions, negotiated underwritings, secondary distributions of listed and unlisted securities, private placements, leveraged buyouts, and valuations for estate, corporate and other purposes. Lazard in the past has provided and in the future may provide investment banking services to Critical Therapeutics, for which Lazard has received and may receive compensation, including having acted as exclusive financial advisor to Critical Therapeutics in connection with a licensing transaction in 2007, for which Lazard was paid an aggregate fee of approximately $1.2 million. In addition, Lazard Capital Markets LLC, or LCM, an entity indirectly owned in large part by managing directors of Lazard, acted as sole placement agent in connection with an equity offering of Critical Therapeutics in 2006, for which LCM was paid an aggregate fee of approximately $1.2 million, a portion of which was paid by LCM to Lazard as a referral fee. In the ordinary course of their respective businesses, affiliates of Lazard and LCM may actively trade securities of Critical Therapeutics for their own accounts and for the accounts of their customers and, accordingly, may at any time hold a long or short position in such securities.

Lazard is an internationally recognized investment banking firm providing a full range of financial advisory and securities services. Lazard was selected to act as Critical Therapeutics financial advisor because of its qualifications, experience and reputation in investment banking and mergers and acquisitions and its familiarity with Critical Therapeutics.

Lazard prepared the above analyses for the purpose of providing an opinion to Critical Therapeutics board of directors as to the fairness, from a financial point of view, to Critical Therapeutics of the exchange ratio. Lazard did not recommend any specific consideration to Critical Therapeutics board of directors or that any given consideration constituted the only appropriate consideration for the merger.

Lazard s opinion and analyses were only one of many factors taken into consideration by Critical Therapeutics board of directors in its evaluation of the merger. Consequently, the analyses described above should not be viewed as determinative of the views of Critical Therapeutics board of directors or Critical Therapeutics management with respect to the exchange ratio or as to whether Critical Therapeutics board of directors would have been willing to determine that a different consideration was fair.

**Interests of Critical Therapeutics Directors and Executive Officers in the Merger**

In considering the recommendation of Critical Therapeutics board of directors with respect to issuing shares of Critical Therapeutics common stock as contemplated by the merger agreement and the other matters to be acted upon by Critical Therapeutics stockholders at the special meeting, Critical Therapeutics stockholders should be aware that members of the board of directors and executive officers of Critical Therapeutics have interests in the merger that are different from, or in addition to, the interests of Critical Therapeutics stockholders. Critical Therapeutics and Cornerstone s boards of directors were aware of these potential conflicts of interest and considered them, among other matters, in reaching their respective decisions to approve the merger agreement and the merger, in the case of Cornerstone s board of directors, to recommend that Cornerstone s stockholders vote to adopt the merger agreement, and, in the case of Critical Therapeutics board of directors, to recommend that Critical Therapeutics stockholders vote to approve the issuance of Critical Therapeutics common stock in connection with the merger and the other matters to be acted upon by Critical Therapeutics stockholders at the special meeting.

***Ownership Interests***

Assuming that the merger had been consummated on September 15, 2008, the beneficial ownership and other equity interests in the combined company immediately following the merger of Mr. Townsend, who is

Table of Contents

expected to serve as General Counsel, Executive Vice President of Legal Affairs and Secretary of the combined company, are expected to be as set forth below:

| Name | Total Shares Beneficially Owned | Total Options Held | Options Exercisable Within 60 Days | Company Beneficial Ownership Percentage |
|---|---|---|---|---|
| Scott B. Townsend(1) | 1,751,672 | 244,000 | 167,015 | 1.4% |

(1) In anticipation of Mr. Townsend s service to the combined company following the merger, on September 16, 2008, Critical Therapeutics entered into a restricted stock agreement that provides for a restricted stock grant to Mr. Townsend on the first business day after the consummation of the merger of a number of shares of common stock representing one percent of the combined company s outstanding equity, on a fully diluted basis but excluding an aggregate of 7,208,707 shares of Critical Therapeutics common stock underlying warrants issued in connection with a June 2005 private placement and an October 2006 registered offering, after giving effect to the reverse stock split and the merger. The restricted stock agreement will only become effective if the merger is consummated. It is expected that approximately 1,489,789 shares will be issued to Mr. Townsend pursuant to the restricted stock agreement, subject to adjustment as a result of the reverse stock split.

As of September 15, 2008, all directors and executive officers of Critical Therapeutics, together with their affiliates, beneficially owned approximately 23.2% of the shares of Critical Therapeutics common stock. The affirmative vote of the holders of a majority of the shares of Critical Therapeutics common stock present in person or represented by proxy and voting on such matter at the special meeting is required for approval of Proposal 1 and Proposal 4. The affirmative vote of holders of a majority of the outstanding shares of Critical Therapeutics common stock as of the record date for the special meeting is required for approval of Proposal 2 and Proposal 3.

***Employment Agreements***

Critical Therapeutics has entered into employment agreements with each of its executive officers. In December 2004, Critical Therapeutics entered into employment agreements with Dr. Phillips and Mr. Townsend. In June 2006, Critical Therapeutics entered into an employment agreement with Jeffrey E. Young, Vice President of Finance, Chief Accounting Officer and Treasurer. In August 2007, Critical Therapeutics entered into an employment agreement with Mr. Kelly. In November 2007, Critical Therapeutics entered into amended and restated employment agreements with Dr. Phillips, Mr. Townsend and Mr. Young. In April 2008, Critical Therapeutics entered into a further amended and restated employment agreement with Dr. Phillips in connection with his appointment as President and Chief Executive Officer.

Each of the employment agreements with its current executive officers, other than with Mr. Kelly, has an initial term that extends through December 31, 2009. Mr. Kelly s employment agreement has an initial term that extends through December 31, 2008. Each of these employment agreements automatically extends for an additional one-year term after the initial term unless either Critical Therapeutics or the executive officer gives 90-days prior notice.

Under the employment agreements, each executive officer is paid a base salary and is eligible for an annual cash bonus of a specified percentage of his annual base salary and an annual equity award. The employment agreements provide for an annual base salary of $330,000 for Dr. Phillips, $279,500 for Mr. Kelly, $275,000 for Mr. Townsend and $202,800 for Mr. Young and an annual target cash bonus as a percentage of base salary of 40% for Dr. Phillips,

30% for Mr. Kelly, 30% for Mr. Townsend and 30% for Mr. Young.

Each employment agreement with the current executive officers of Critical Therapeutics provides that if Critical Therapeutics terminates the executive officer s employment other than for cause or if the executive officer terminates his employment for good reason, in each case as those terms are defined in his employment agreement, then Critical Therapeutics is obligated to provide the following to the executive

Table of Contents

officer, provided such person executes and delivers to Critical Therapeutics a severance agreement and release drafted by and satisfactory to counsel to Critical Therapeutics:

- a lump sum payment equal to his annual base salary in effect at that time for each executive officer other than Dr. Phillips, and a lump sum payment equal to 1.25 times his annual base salary in effect at that time for Dr. Phillips;

- monthly payments in the amount of 100% of the monthly COBRA premiums for continued health and dental coverage for the executive officer and his dependents for each executive officer other than Mr. Kelly, and 80% of the monthly COBRA premiums for continued health and dental coverage for Mr. Kelly and his dependents, and 100% of the amount of the monthly premiums paid by Critical Therapeutics for life insurance and disability insurance for the executive officer until the earlier of one year, or in the case of Dr. Phillips 15 months, after termination or the last day of the first month when such officer is eligible for benefits through other employment;

- a pro rata payment of his target cash bonus in effect in the year of termination; and

- accelerated vesting of 50% of his outstanding unvested stock options and restricted stock.

Immediately upon a change of control of Critical Therapeutics, as defined in his employment agreement, each executive officer is entitled to accelerated vesting of 50% of all his outstanding unvested stock options and restricted stock. In addition, Dr. Phillips is entitled to receive a one-time lump sum payment of $175,000 upon a change of control.

If Critical Therapeutics terminates the executive officer s employment other than for cause or if the executive officer terminates his employment for good reason during the period from three months before until one year after the occurrence of a change of control, then Critical Therapeutics is obligated to provide the following to the executive officer, provided such person executes and delivers to Critical Therapeutics a severance agreement and release drafted by and satisfactory to counsel to Critical Therapeutics:

- lump sum payment equal to his annual base salary in effect at that time for each executive officer other than Dr. Phillips, and a lump sum payment equal to 1.5 times his annual base salary in effect at that time for Dr. Phillips;

- monthly payments in the amount of 100% of the monthly COBRA premiums for continued health and dental coverage for the executive officer and his dependents for each executive officer other than Mr. Kelly and 80% of the monthly COBRA premiums for continued health and dental coverage for Mr. Kelly and his dependents, and 100% of the amount of the monthly premiums paid by Critical Therapeutics for life insurance and disability insurance for the executive officer until the earlier of one year, or in the case of Dr. Phillips 18 months, after termination or the last day of the first month when such officer is eligible for benefits through other employment;

- a pro rata payment of his target cash bonus in effect in the year of termination;

- accelerated vesting of 100% of his outstanding unvested stock options and restricted stock; and

- up to three months of outplacement services.

Upon voluntary resignation, each executive officer is entitled to a pro rata payment of his annual bonus from the previous year provided that the executive officer gives 90-days prior written notice of resignation and executes a release of Critical Therapeutics.

Each executive officer has agreed not to compete with Critical Therapeutics during his employment with Critical Therapeutics and for a one-year period after termination of employment by Critical Therapeutics for any reason or after a change of control of Critical Therapeutics. In the event of a breach of this non-competition obligation, Critical Therapeutics will be entitled to injunctive relief in addition to any other remedies it might have, and the executive will continue to be held to the obligation until the requisite time period has passed without any violation. Each executive officer has also agreed not to disclose any confidential information obtained during his employment. The severance agreements and releases used by

Table of Contents

Critical Therapeutics typically contain provisions, whereby a departing executive reaffirms these obligations, and non-disparagement clauses of perpetual duration, compliance with which is a condition to the receipt of payments.

In anticipation of Mr. Townsend s service to the combined company following the merger, on September 16, 2008, Critical Therapeutics entered into an amendment to the amended and restated employment agreement between Critical Therapeutics and Mr. Townsend. This amendment will be effective from the effective time of the merger to December 31, 2010 and will only become effective if the merger is consummated. Under the terms of this amendment, Mr. Townsend will serve as the General Counsel, Executive Vice President of Legal Affairs and Secretary of the combined company. The amendment provides for an increase in Mr. Townsend s annual target cash bonus as a percentage of base salary from 30% to 35% and an actual annual cash bonus for Mr. Townsend for 2008 of not less than 35% of his base salary if he remains an employee in good standing through December 31, 2008. Mr. Townsend will continue to receive an annual base salary of $275,000. Mr. Townsend also will be eligible to participate in all of the combined company s benefit plans and programs, including a car allowance, as provided to other vice president or executive vice president level executives at Cornerstone. Because it is expected that Mr. Townsend may, for some period of time, continue to reside in Massachusetts following the relocation of the combined company to North Carolina, Mr. Townsend also will be reimbursed for related business travel expenses and temporary lodging while in North Carolina and expenses related to a home office in Massachusetts.

In connection with such amendment, on September 16, 2008, Critical Therapeutics also entered into a restricted stock agreement with Mr. Townsend that provides for a restricted stock grant to Mr. Townsend on the first business day after the consummation of the merger of a number of shares of common stock representing one percent of the combined company s outstanding equity, on a fully diluted basis but excluding an aggregate of 7,208,707 shares of Critical Therapeutics common stock underlying warrants issued in connection with a June 2005 private placement and an October 2006 registered offering, after giving effect to the reverse stock split and the merger, subject to the terms of such restricted stock agreement. The restricted stock agreement will only become effective if the merger is consummated. It is expected that approximately 1,489,789 shares will be issued to Mr. Townsend pursuant to the restricted stock agreement, subject to adjustment as a result of the reverse stock split. This restricted stock award will vest as to 25% of the shares subject to the award on May 1, 2009, 25% of the shares on May 1, 2010, 25% of the shares on May 1, 2011 and 25% of the shares on May 1, 2012.

The amendment to Mr. Townsend s amended and restated employment agreement specifically recognizes that the relocation of the combined company to North Carolina constitutes good reason under his amended and restated employment agreement. Accordingly, the amendment provides that if Mr. Townsend s employment is terminated at any time on or before December 31, 2009 by the combined company without cause, by Mr. Townsend for good reason or because of Mr. Townsend s death or disability, the combined company will provide to Mr. Townsend or his estate, as applicable, the payments and benefits described above pursuant to his existing amended and restated employment agreement. However, if Mr. Townsend resigns his employment for good reason prior to December 31, 2009 related to the relocation of the combined company, the accelerated vesting of his outstanding unvested stock options and restricted stock will not include the restricted stock granted pursuant to the restricted stock agreement dated September 16, 2008. If Mr. Townsend s employment is terminated by the combined company without cause prior to December 31, 2009, then vesting will accelerate with respect to 35% of the restricted stock granted pursuant to the restricted stock agreement dated September 16, 2008, unless such termination is during a change of control period relating to a transaction other than the merger with Cornerstone, in which case, the vesting will accelerate with respect to 100% of the restricted stock granted pursuant to the restricted stock agreement dated September 16, 2008. Mr. Townsend would be entitled to the payments and benefits described above pursuant to his existing amended and restated employment agreement if his employment is terminated after December 31, 2009 by the combined company without cause or by Mr. Townsend for good reason not related to the relocation of the combined company.

Table of Contents

***Cash Bonus Awards Upon a Change in Control***

On July 16, 2008, based on the recommendation of the compensation committee, Critical Therapeutics board of directors established a bonus program for Critical Therapeutics executive officers providing for Critical Therapeutics to pay cash bonuses to its executive officers, other than Dr. Phillips, who remain employed with Critical Therapeutics and satisfactorily perform their job duties, as determined by Critical Therapeutics, upon the consummation of the merger or any other change in control of Critical Therapeutics, as defined in Critical Therapeutics 2004 Stock Incentive Plan, as amended. This cash bonus also would be payable if Critical Therapeutics terminates an executive officer s employment without cause, as defined in his employment agreement, within 28 days before the occurrence of a change in control, provided the executive officer executes and delivers to Critical Therapeutics a severance agreement and release drafted by and satisfactory to Critical Therapeutics. These cash bonuses are in addition to compensation and benefits otherwise payable to these executive officers under their employment agreements. Under this bonus program, the executive officers listed below are entitled to the following bonus amounts:

| Name | Cash Bonus Amount |
|---|---|
| Thomas P. Kelly | $ 45,000 |
| Scott B. Townsend, Esq. | 50,000 |
| Jeffrey E. Young | 35,000 |

As discussed above, pursuant to the terms of his employment agreement, Dr. Phillips is separately entitled to receive a lump sum payment of $175,000 upon a change in control of Critical Therapeutics, as defined in his employment agreement.

***Summary of Potential Payments in Connection with the Merger***

Promptly following the effective time of the merger, the executive management team of the combined company is expected to be composed primarily of current Cornerstone executives, except that Mr. Townsend is expected to serve as General Counsel, Executive Vice President of Legal Affairs and Secretary of the combined company. Accordingly, it is contemplated that Critical Therapeutics executive officers will be entitled to payments in connection with the consummation of the merger, which constitutes a change in control under each executive s employment agreement and Critical Therapeutics 2004 Stock Incentive Plan, as amended.

The following table sets forth information regarding payments and benefits that each executive officer of Critical Therapeutics would receive in connection with the consummation of the merger pursuant to the terms of his employment agreement or the change of control cash bonus program described above, as applicable, assuming that the merger had been consummated on September 15, 2008 and, as applicable, such executive s employment was terminated on such date.

| | Immediately Upon a Change of Control | | | Termination in Connection with a Change of Control | | | |
|---|---|---|---|---|---|---|---|
| Name | Cash Payment | Value of Options with Accelerated Vesting(1) | Value of Stock with Accelerated Vesting(2) | Cash Payments(3) | Value of Benefits(4) | Value of Options with Accelerated Vesting(1) | Value of Stock with Accelerated Vesting(2) |

| | | | | | |
|---|---|---|---|---|---|
| Trevor Phillips, Ph.D. | $ 175,000 | $ 4,654 | $ 756,625 | $ 29,650 | $ 9,308 |
| Thomas P. Kelly | 45,000 | 4,747 | 387,388 | 16,145 | 9,494 |
| Scott B. Townsend, Esq.(5) | 50,000 | 4,747 | 386,875 | 21,375 | 9,494 |
| Jeffrey E. Young | 35,000 | 2,831 | 283,430 | 20,981 | 5,661 |

(1) The amounts in this column are calculated based on the difference between $0.22, the closing market price per share of Critical Therapeutics common stock on September 15, 2008, and the exercise price per share of the options subject to accelerated vesting. All options subject to accelerated vesting have an exercise price greater than $0.22 per share.

Table of Contents

(2) The amounts in this column are calculated by multiplying the number of shares subject to accelerated vesting by $0.22, the closing market price per share of Critical Therapeutics common stock on September 15, 2008.

(3) The amounts in this column reflect (i) a lump sum payment equal to annual base salary in effect on September 15, 2008, or in the case of Dr. Phillips, a lump sum payment equal to 1.5 times annual base salary in effect on September 15, 2008, and (ii) a pro rata payment of the target cash bonus for 2008 for the executive officer. The amount for Dr. Phillips includes the $175,000 payment that he would be entitled to receive under his employment agreement upon the consummation of a change in control. The amount for each other executive officer includes the payment that such executive officer would be entitled to receive under the change in control cash bonus program.

(4) The amounts in this column reflect 12 monthly payments in the amount of (i) 100% of the monthly COBRA premiums for continued health and dental coverage for the executive officer and his dependents, or 80% in the case of Mr. Kelly, and (ii) 100% of the amount of life insurance and disability insurance for the executive officer in the month prior to termination for 12 months, or 18 months in the case of Dr. Phillips, if Critical Therapeutics terminates his employment other than for cause or if he terminates his employment for good reason during the period from three months before until one year after the occurrence of a change of control. In addition, the amounts in this column include $5,000, which is an estimate of the fair market value of up to three months of outplacement services that would be provided to such executives if Critical Therapeutics terminates the executive s employment other than for cause or if an executive terminates his employment for good reason during the period from three months before until one year after the occurrence of a change of control.

(5) Mr. Townsend is expected to serve as General Counsel, Executive Vice President of Legal Affairs and Secretary of the combined company.

***Director Stock Option Agreements***

Critical Therapeutics directors Jean George and Richard W. Dugan are parties to stock option agreements with Critical Therapeutics that provide for accelerated vesting of the stock options granted pursuant to such agreements upon a change of control of Critical Therapeutics. All stock options subject to accelerated vesting have an exercise price that is greater than $0.22 per share, the closing market price per share of Critical Therapeutics common stock on September 15, 2008.

***Indemnification of Officers and Directors***

The merger agreement provides that, for a period of six years following the effective time of the merger, Critical Therapeutics will, to the fullest extent permitted by law, indemnify and hold harmless each present and former director and officer of Critical Therapeutics against any costs or expenses (including attorneys fees), judgments, fines, losses, claims, damages, liabilities or amounts paid in settlement incurred in connection with any claim, action, suit, proceedings or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to matters existing or occurring at or prior to the effective time of the merger, whether asserted or claimed prior to, at or after the effective time of the merger, to the fullest extent that Critical Therapeutics or one of its subsidiaries, as the case may be, would have been permitted under Delaware law and its certificate of incorporation or bylaws.

The merger agreement also provides that, for a period of six years following the effective time of the merger, Critical Therapeutics will maintain in effect a directors and officers liability insurance policy covering the directors and officers of Critical Therapeutics, with coverage in amount and scope at least as favorable as the coverage under Critical Therapeutics existing policy as of the time the merger becomes effective. If the annual premiums payable for

such insurance coverage exceed 150% of the current annual premiums paid by Critical Therapeutics for its existing policy, Critical Therapeutics will provide the maximum coverage that will then be available at an annual premium equal to 150% of such rate.

Table of Contents

**Interests of Cornerstone s Directors and Executive Officers in the Merger**

Members of the board of directors and executive officers of Cornerstone may have interests in the merger that are different from, or are in addition to, the interests of Cornerstone s stockholders generally. These interests generally include, among other things, the potential for such persons to occupy positions as officers or directors of the combined company and the potential benefits under employment or severance arrangements as a result of the merger. The Cornerstone board of directors was aware of these interests and considered them, among other matters, in approving the merger agreement and in determining to recommend that Cornerstone s stockholders vote to approve and adopt the merger agreement.

***Board of Directors and Management***

Craig A. Collard is the Chief Executive Officer and a member of the board of directors of Cornerstone and, upon closing of the merger, Mr. Collard will become the President, Chief Executive Officer and a director of the combined company. Mr. Collard participated in the negotiation and approval of the terms of the merger on behalf of Cornerstone.

Following the merger, in addition to Mr. Collard, certain other directors and members of the senior management of Cornerstone will assume new positions with the combined company. Alastair McEwan is the Chairman of Cornerstone and, upon closing of the merger, will become a director of the combined company. Chenyqua Baldwin is the Vice President of Finance of Cornerstone and, upon closing of the merger, will become the Chief Accounting Officer, Controller and Vice President of Finance of the combined company. Brian Dickson, M.D. is the Chief Medical Officer of Cornerstone and, upon the closing of the merger, will hold the same position in the combined company. George Esgro is the Vice President of Sales and Marketing of Cornerstone and, upon the closing of the merger, will hold the same position in the combined company. Steven M. Lutz is the Executive Vice President of Commercial Operations of Cornerstone and, upon closing of the merger, will become the Executive Vice President of Manufacturing and Trade in the combined company. David Price became the Executive Vice President, Finance, and Chief Financial Officer of Cornerstone on September 8, 2008, and will hold the same positions in the combined company. Mr. McEwan, Ms. Baldwin, Dr. Dickson, Mr. Esgro, Mr. Lutz and Mr. Price participated in the negotiation of the terms of the merger. For a more complete description of the management of the combined company after the merger, please see the section Management Following the Merger beginning on page 294 of this proxy statement/prospectus.

***Ownership Interests***

As of September 15, 2008, all directors and executive officers of Cornerstone, together with their associates, held interests in 18,295,000 shares of Cornerstone s common stock representing approximately 73.4% of Cornerstone s issued and outstanding common stock as of such date, including 13,450,000 shares owned by Cornerstone Biopharma Holdings, Ltd., an entity which is wholly-owned by Mr. Collard, and 1,250,000 shares owned by the Craig Collard Irrevocable Trust, a trust in which Mr. Collard has a substantial beneficial interest.

Assuming that the merger had been consummated on September 15, 2008, Cornerstone s executive officers and directors, and their affiliates, would beneficially own, in the aggregate, approximately 51% of the outstanding common stock of the combined company, including any shares of the common stock of the combined company issuable in the merger in exchange for shares of Cornerstone s outstanding common stock to be issued to Carolina Pharmaceuticals upon the exchange or conversion prior to the merger of the outstanding principal amount under the Carolina Note into shares of Cornerstone s common stock pursuant to the noteholder agreement between Carolina

Pharmaceuticals and Critical Therapeutics. Additionally, Cornerstone s executive officers and directors would hold certain options to acquire shares of the common stock of the combined company that are not considered beneficially owned because such options are not exercisable within sixty days of September 15, 2008. Assuming that the merger had been consummated on September 15, 2008 and assuming an exchange ratio of

Table of Contents

2.448566, the beneficial ownership and other equity interests of Cornerstone s executive officers and directors, and their affiliates, in the combined company immediately following the merger are expected to be as set forth below:

| Name | Total Shares Beneficially Owned | Total Options Held | Options Exercisable Within 60 Days | Combined Company Beneficial Ownership Percentage |
|---|---|---|---|---|
| Craig A. Collard(1) | 48,091,789 | 2,569,839 | 734,239 | 38.2% |
| Chenyqua Baldwin | 2,429,109 | 2,055,871 | 593,510 | 1.9 |
| Brian Dickson, M.D. | 1,636,742 | 3,671,199 | 1,636,742 | 1.3 |
| George Esgro(2) | | 734,239 | | |
| Steven M. Lutz | 7,651,389 | 2,263,906 | 688,349 | 6.1 |
| Alastair McEwan | 2,753,399 | 3,671,199 | 2,753,399 | 2.2 |
| David Price(3) | 3,186,052 | | | 2.5 |

(1) Total shares beneficially owned consists of 32,933,206 shares of common stock held by Cornerstone BioPharma Holdings, Ltd., 14,439,134 shares of common stock held by Carolina Pharmaceuticals received in connection with the conversion of the outstanding principal amount under the Carolina Note and options to purchase 734,569 shares of common stock pursuant to stock option grants awarded to Mr. Collard under Cornerstone s 2005 Stock Incentive Plan. Mr. Collard is the controlling shareholder and a director of Cornerstone Biopharma Holdings, Ltd. and by virtue of such positions will exercise voting and investment power with respect to the shares of the combined company to be owned by Cornerstone Biopharma Holdings, Ltd. following the merger. Mr. Collard is the chief executive officer and chairman of the board of Carolina Pharmaceuticals and by virtue of such positions will exercise voting and investment power with respect to the shares of the combined company to be owned by Carolina Pharmaceuticals following the merger.

(2) Pursuant to the Employment Agreement, dated March 3, 2008, between Cornerstone and Mr. Esgro, Cornerstone is obligated to grant Mr. Esgro an option to purchase 300,000 shares of Cornerstone s common stock. Cornerstone expects that the option award to Mr. Esgro will be completed immediately prior to the effective time of the merger.

(3) Mr. Price became the Executive Vice President, Finance, and Chief Financial Officer of Cornerstone effective as of September 8, 2008. Pursuant to the Executive Employment Agreement, dated August 20, 2008, between Cornerstone and Mr. Price, Cornerstone is obligated to issue to Mr. Price 1,301,776 restricted shares of Cornerstone common stock. Cornerstone expects that this restricted stock award to Mr. Price will be completed immediately prior to the effective time of the merger. In connection with the merger, Mr. Price s 1,301,776 restricted shares of Cornerstone common stock will be converted into restricted shares of the combined company s common stock.

For a more complete description of the ownership interests of the executive officers and directors of Cornerstone, please see the sections entitled Principal Stockholders of Cornerstone beginning on page 347 of this proxy statement/prospectus and Principal Stockholders of Combined Company beginning on page 349 of this proxy statement/prospectus.

***Stock Options***

Under the terms of the merger agreement, at the effective time of the merger, each outstanding option to purchase shares of Cornerstone common stock, whether vested or unvested, will be assumed by Critical Therapeutics and will become an option to acquire, on the same terms and conditions as were applicable under the stock option agreement by which such option is evidenced and the stock option plan under which such option was issued, if any, shares of Critical Therapeutics common stock. The number of shares of Critical Therapeutics common stock subject to each assumed option will be determined by multiplying the number of shares of Cornerstone common stock that was subject to each option prior to the effective time of the merger by an exchange ratio determined pursuant to the merger agreement, and rounding that result down

Table of Contents

to the nearest whole number of shares of Critical Therapeutics common stock. The per share exercise price for the assumed options will be determined by dividing the per share exercise price of the Cornerstone common stock subject to each option as in effect immediately prior to the effective time of the merger by the exchange ratio and rounding that result up to the nearest whole cent. The exact exchange ratio per share of Cornerstone s common stock will be based in part on the number of shares of Cornerstone s common stock outstanding on a fully diluted basis immediately prior to the effective time of the merger and will not be calculated until that time. For a more complete description of the merger, please see the section entitled The Merger Agreement beginning on page 137 of this proxy statement/prospectus.

The table below sets forth, as of September 15, 2008, information with respect to options held by each of Cornerstone s executive officers and directors:

| Name | Total Options Held | Vested | Unvested | Weighted Average Exercise Price Per Share |
|---|---|---|---|---|
| Craig A. Collard | 1,050,000 | 300,000 | 750,000 | $ 0.40 |
| Chenyqua Baldwin | 840,000 | 242,500 | 597,500 | 0.39 |
| Brian Dickson, M.D. | 1,500,000 | 668,750 | 831,250 | 0.26 |
| George Esgro(1) | | | | |
| Steven M. Lutz | 925,000 | 281,250 | 643,750 | 0.36 |
| Alastair McEwan | 1,500,000 | 1,125,000 | 375,000 | 0.21 |
| David Price(2) | | | | |

(1) Pursuant to the Employment Agreement, dated March 3, 2008, between Cornerstone and Mr. Esgro, Cornerstone is obligated to grant Mr. Esgro an option to purchase 300,000 shares of Cornerstone s common stock. Cornerstone expects that the option award to Mr. Esgro will be completed immediately prior to the effective time of the merger.

(2) Mr. Price entered into an Employment Agreement with Cornerstone pursuant to which he became the Executive Vice President, Finance, and Chief Financial Officer of Cornerstone, effective September 8, 2008. Mr. Price also entered into a Restricted Stock Agreement pursuant to which he will receive 1,301,776 shares of restricted stock of Cornerstone immediately prior to the consummation of the merger with Critical Therapeutics. The restricted stock will vest 25% on each of the first four anniversaries of August 20, 2008.

***Noteholder Agreement with Carolina Pharmaceuticals***

In April 2004, Cornerstone entered into the Carolina Note, an unsecured loan agreement with Carolina Pharmaceuticals, whereby Cornerstone could borrow up to $15.0 million at 10% interest for five years. Because Mr. Collard is the Chief Executive Officer and Chairman of the Board of Carolina Pharmaceuticals, he is a control person of Carolina Pharmaceuticals. In addition, Ms. Baldwin and Mr. Lutz are each directors of Carolina Pharmaceuticals. Cornerstone borrowed $13.0 million under the Carolina Note in April 2004. In June 2006, Cornerstone entered into a note amendment and waiver agreement that provided for the offset of approximately $3.6 million in principal and $1.8 million in accrued interest outstanding under the Carolina Note against equal amounts due to Cornerstone from Cornerstone Biopharma Holdings, Ltd. and Carolina Pharmaceuticals. The amounts

due to Cornerstone primarily resulted from the 2005 Adams litigation settlement. As of December 31, 2007 and 2006, approximately $9.4 million in principal was outstanding under the Carolina Note plus approximately $549,000 and $1.5 million in accrued interest, respectively. On April 11, 2008, Cornerstone made a principal payment of $460,000 on the Carolina Note. The outstanding principal and accrued interest are due in 2009. As of September 15, 2008, the outstanding principal amount of the Carolina Note was approximately $9.0 million.

Carolina Pharmaceuticals, which is the holder of the Carolina Note, has entered into an agreement that provides, among other things, for the exchange or conversion of the outstanding principal amount of the Carolina Note into approximately 18% of the shares of Cornerstone s common stock outstanding immediately

Table of Contents

prior to the effective time of the merger and for the same voting and lock-up provisions provided pursuant to the agreements entered into by Cornerstone s other stockholders.

***Employment and Related Agreements***

Cornerstone is party to employment agreements with its executive officers. These agreements provide that the executive officer is entitled to minimum annual base salary, an annual bonus, severance, and certain health, retirement, and other benefits. The material terms of these agreements have been summarized in the section Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table beginning on page 312 of this proxy statement/prospectus. The individuals who are parties to these agreements, as well as their positions and annual base salaries, are as follows: (i) Craig A. Collard, President and Chief Executive Officer, annual base salary of $379,600; (ii) Chenyqua Baldwin, Vice President, Finance, annual base salary of $223,600; (iii) Brian Dickson, M.D., Chief Medical Officer, annual base salary of $270,400; (iv) George Esgro, Vice President, Sales and Marketing, annual base salary of $220,000; (v) Steven M. Lutz, Executive Vice President, Commercial Operations, annual base salary of $250,000; and (vi) David Price, Executive Vice President, Finance, and Chief Financial Officer, annual base salary of $285,000.

In addition to his employment agreement, Mr. Collard has entered into an Executive Retention Agreement that provides for certain severance benefits in the event that his employment is terminated following a change in control of Cornerstone. The material terms of this agreement have been summarized in the section Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table beginning on page 312 of this proxy statement/prospectus.

***Stockholder Agreements***

In connection with the execution of the merger agreement, Mr. Collard, Ms. Baldwin, Dr. Dickson, Mr. Esgro, Mr. Lutz, Mr. McEwan and other holders of Cornerstone shares that in the aggregate hold approximately 81% of Cornerstone s outstanding common stock entered into agreements with Critical Therapeutics that provide, among other things, that they will vote in favor of adoption of the merger agreement and grant to Critical Therapeutics an irrevocable proxy to vote all of their shares of Cornerstone common stock in favor of adoption of the merger agreement and against any proposal made in opposition to, or in competition with, the proposal to adopt the merger agreement. In addition, subject to certain exceptions, they have agreed not to transfer or otherwise dispose of any shares of common stock of the combined company or any securities convertible into or exercisable or exchangeable for shares in the combined company for 180 days after the effective time of the merger.

**Cornerstone Stock Options and Warrants**

Each outstanding option to purchase shares of Cornerstone common stock, whether vested or unvested, and all stock option plans or other stock or equity-related plans of Cornerstone themselves, insofar as they relate to outstanding Cornerstone s stock options, will be assumed by Critical Therapeutics and will become an option to acquire, on the same terms and conditions as were applicable under such Cornerstone stock option immediately prior to the effective time of the merger, such number of shares of Critical Therapeutics common stock as is equal to the number of shares of Cornerstone subject to the unexercised portion of such Cornerstone stock option immediately prior to the effective time of the merger multiplied by the exchange ratio (rounded down to the nearest whole share number), at an exercise price per share equal to the exercise price per share of such Cornerstone stock option immediately prior to the effective time of the merger divided by the exchange ratio (rounded up to the nearest whole cent).

At the effective time of the merger, each warrant to purchase shares of Cornerstone common stock outstanding immediately prior to the effective time of the merger will be assumed by Critical Therapeutics and will become a

warrant to acquire, on the same terms and conditions as were applicable under such Cornerstone warrant, such number of shares of Critical Therapeutics common stock as is equal to the number of shares of Cornerstone s common stock subject to the unexercised portion of such Cornerstone warrant immediately prior to the effective time of the merger multiplied by the exchange ratio (rounded down to the nearest whole share number), at an exercise price per share equal to the exercise price per share of such Cornerstone warrant

Table of Contents

immediately prior to the effective time of the merger divided by the exchange ratio (rounded up to the nearest whole cent).

**Form of the Merger**

Under the merger agreement, Cornerstone and the transitory subsidiary will merge, with Cornerstone surviving as a wholly owned subsidiary of Critical Therapeutics.

After completion of the merger, Critical Therapeutics will be renamed Cornerstone Therapeutics Inc. and expects to continue to trade on The NASDAQ Capital Market under the symbol CRTX.

Following the merger, the headquarters of Critical Therapeutics will be located in Cary, North Carolina, at Cornerstone s headquarters.

**Merger Consideration**

At the effective time of the merger, all shares of Cornerstone common stock outstanding immediately prior to the effective time of the merger, including shares of Cornerstone common stock issued or issuable to Carolina Pharmaceuticals for the exchange or conversion of the outstanding principal amount of the Carolina Note, will automatically be converted into the right to receive shares of Critical Therapeutics common stock. In addition, at the effective time of the merger, all options to purchase shares of Cornerstone common stock outstanding immediately prior to the effective time of the merger will be assumed by Critical Therapeutics and will become options to purchase shares of Critical Therapeutics common stock and all warrants to purchase shares of Cornerstone common stock outstanding immediately prior to the effective time of the merger will be assumed by Critical Therapeutics and will become warrants to purchase shares of Critical Therapeutics common stock. The shares of Critical Therapeutics common stock issued to Cornerstone s stockholders in connection with the merger are expected to represent approximately 70%, and Critical Therapeutics current stockholders will own approximately 30%, of the shares of Critical Therapeutics common stock, assuming the exchange or conversion prior to the merger of the outstanding principal amount of the Carolina Note into shares of Cornerstone s common stock and after giving effect to shares issuable pursuant to Cornerstone s outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics outstanding options and warrants. The exact exchange ratio per share of Cornerstone s common stock will be based in part on the number of shares of Cornerstone s common stock outstanding or issuable pursuant to outstanding options and warrants immediately prior to the effective time of the merger and will not be calculated until that time.

No certificate or scrip representing fractional shares of Critical Therapeutics common stock will be issued in connection with the merger. Each holder of Cornerstone s common stock who would otherwise have been entitled to receive a fraction of a share of Critical Therapeutics common stock (after taking into account all shares of Cornerstone s common stock represented by certificates delivered by such holder) shall be entitled to receive, in lieu thereof, cash (without interest) in an amount equal to such fractional part of a share of Critical Therapeutics common stock multiplied by the average last reported sales price of Critical Therapeutics common stock at 4:00 p.m., Eastern time, end of regular trading hours on NASDAQ during the 10 consecutive trading days ending on the last trading day prior to the effective date of the merger.

The merger agreement provides that, at the effective time of the merger, Critical Therapeutics will deposit with BNY Mellon Shareowner Services or another exchange agent designated by Critical Therapeutics and reasonably acceptable to Cornerstone stock certificates representing the shares of Critical Therapeutics common stock issuable to Cornerstone s stockholders, a sufficient amount of cash to make payments in lieu of fractional shares, and any dividend or distributions to which holders of such stock certificates may be entitled.

The merger agreement provides that, as soon as reasonably practicable after the effective time of the merger, the exchange agent will mail to each record holder of Cornerstone common stock immediately prior to the effective time of the merger a letter of transmittal and instructions for surrendering and exchanging the record holder s Cornerstone stock certificates. Upon surrender of a Cornerstone common stock certificate for exchange to the exchange agent, together with a duly signed letter of transmittal, and such other documents as

Table of Contents

the exchange agent may reasonably require, the holder of the Cornerstone stock certificate will be entitled to receive the following:

a certificate representing the number of whole shares of Critical Therapeutics common stock that such holder has the right to receive pursuant to the provisions of the merger agreement;

cash in lieu of any fractional share of Critical Therapeutics common stock; and

dividends or other distributions, if any, to which they are entitled under the terms of the merger agreement.

The Cornerstone stock certificate surrendered will be cancelled.

At the effective time of the merger, all holders of certificates representing shares of Cornerstone s common stock that were outstanding immediately prior to the effective time of the merger will cease to have any rights as stockholders of Cornerstone. In addition, no transfer of Cornerstone s common stock after the effective time of the merger will be registered on the stock transfer books of Cornerstone.

If any Cornerstone stock certificate has been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming such certificate to be lost, stolen or destroyed and, if required by Critical Therapeutics, the posting by such person of a bond in such reasonable amount as Critical Therapeutics may direct as indemnity against any claim that may be made against it with respect to such certificate, the exchange agent shall issue in exchange for such lost, stolen or destroyed certificate the shares of Critical Therapeutics common stock, any cash in lieu of fractional shares, and any unpaid dividends and distributions on such shares of Critical Therapeutics common stock.

**Effective Time of the Merger**

The merger agreement requires the parties to consummate the merger after all of the conditions to the consummation of the merger contained in the merger agreement are satisfied or waived. The merger will become effective upon the filing of a certificate of merger with the Secretary of State of the State of Delaware or at such later time as is established by Critical Therapeutics and Cornerstone and set forth in the certificate of merger. However, neither Critical Therapeutics nor Cornerstone can predict the exact timing of the consummation of the merger.

**Regulatory Approvals**

Neither Critical Therapeutics nor Cornerstone is required to make any filings or to obtain approvals or clearances from any antitrust regulatory authorities in the United States or other countries to consummate the merger. In the United States, Critical Therapeutics must comply with applicable federal and state securities laws and NASDAQ rules and regulations in connection with the issuance of shares of Critical Therapeutics common stock in the merger, including the filing with the SEC of this proxy statement/prospectus. As of the date hereof, the registration statement has not become effective. Critical Therapeutics has filed an initial listing application with The NASDAQ Capital Market pursuant to NASDAQ s reverse merger rules for the re-listing of Critical Therapeutics common stock in connection with the merger and to effect the initial listing of Critical Therapeutics common stock issuable in connection with the merger or upon exercise of Cornerstone s outstanding stock options or warrants.

**Material U.S. Federal Income Tax Consequences of the Merger**

The following discussion summarizes the material U.S. federal income tax consequences of the merger that are expected to apply generally to Cornerstone s stockholders upon an exchange of their Cornerstone common stock for Critical Therapeutics common stock in the merger. This summary is based upon current provisions of the Code,

existing Treasury Regulations and current administrative rulings and court decisions, all of which are subject to change and to differing interpretations, possibly with retroactive effect.

Table of Contents

This summary only applies to a Cornerstone stockholder that is a U.S. person, defined to include:

- a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States, or any political subdivision thereof (including the District of Columbia);
- an estate the income of which is subject to U.S. federal income taxation regardless of its source;
- a trust if either:
  - a court within the United States is able to exercise primary supervision over the administration of such trust and one or more U.S. persons have the authority to control all substantial decisions of such trust; or
  - the trust has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes; and
- any other person or entity that is treated for U.S. federal income tax purposes as if it were one of the foregoing.

Any Cornerstone stockholder other than a U.S. person as so defined is, for purposes of this discussion, a non-U.S. person. If a partnership holds Cornerstone common stock, the tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. If you are a partner of a partnership holding Cornerstone common stock, you should consult your tax advisor.

This summary assumes that Cornerstone s stockholders hold their shares of Cornerstone common stock as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment). No attempt has been made to comment on all U.S. federal income tax consequences of the merger that may be relevant to particular holders, including holders:

- who are subject to special treatment under U.S. federal income tax rules such as dealers in securities, financial institutions, non-U.S. persons, mutual funds, regulated investment companies, real estate investment trusts, insurance companies, employees of Cornerstone who will become employees of Critical Therapeutics, or tax-exempt entities;
- who are subject to the alternative minimum tax provisions of the Code;
- who acquired their shares in connection with stock option or stock purchase plans or in other compensatory transactions;
- who hold their shares as qualified small business stock within the meaning of Section 1202 of the Code;
- who hold their shares as part of an integrated investment such as a hedge or as part of a hedging, straddle or other risk reduction strategy; or
- who do not hold their shares as capital assets.

In addition, the following discussion does not address the tax consequences of the merger under state, local and foreign tax laws or under the alternative minimum tax provisions of the Code. Furthermore, the following discussion does not address any of the:

tax consequences of transactions effectuated before, after or at the same time as the merger, whether or not they are in connection with the merger, including, without limitation, transactions in which Cornerstone shares are acquired or Critical Therapeutics shares are disposed of;

tax consequences of the receipt of Critical Therapeutics shares other than in exchange for Cornerstone shares; or

tax implications of a failure of the merger to qualify as a reorganization.

**Accordingly, holders of Cornerstone common stock are advised and expected to consult their own tax advisers regarding the U.S. federal income tax consequences of the merger to them in light of their personal circumstances and the consequences of the merger under state, local and foreign tax laws.**

Table of Contents

As a condition to the consummation of the merger, WilmerHale and Smith Anderson must render tax opinions that the merger will constitute a reorganization within the meaning of Section 368(a) of the Code, or a reorganization. The tax opinions will be conditioned upon certain assumptions stated in the tax opinions and will be based on the truth and accuracy, as of the completion of the merger, of certain representations and other statements made by Critical Therapeutics and Cornerstone in certificates delivered to counsel. If any such representations and other statements made in such certificates are inaccurate, then the tax opinions may not be valid.

No ruling from the Internal Revenue Service, or IRS, has been or will be requested in connection with the merger. In addition, stockholders of Cornerstone should be aware that the tax opinions discussed in this section are not binding on the IRS, and the IRS could adopt a contrary position and a contrary position could be sustained by a court.

It is intended that the merger will be treated for U.S. federal income tax purposes as a reorganization within the meaning of Section 368(a) of the Code. Accordingly, the following material U.S. federal income tax consequences will result:

- Critical Therapeutics, the transitory subsidiary and Cornerstone will not recognize any gain or loss solely as a result of the merger;

- stockholders of Cornerstone will not recognize any gain or loss upon the receipt of Critical Therapeutics common stock in exchange for their Cornerstone common stock, other than with respect to cash received in lieu of fractional shares of Critical Therapeutics common stock;

- the aggregate tax basis of the shares of Critical Therapeutics common stock received by a Cornerstone stockholder in the merger (including any fractional share deemed received) will be equal to the aggregate tax basis of the shares of Cornerstone common stock surrendered in exchange therefor;

- the holding period of the shares of Critical Therapeutics common stock received by a Cornerstone stockholder in the merger will include the holding period of the shares of Cornerstone common stock surrendered in exchange therefor;

- generally, cash payments received by Cornerstone s stockholders in lieu of fractional shares will be treated as if such fractional shares of Critical Therapeutics common stock were issued in the merger and then sold. A stockholder of Cornerstone who receives such cash will recognize gain or loss equal to the difference, if any, between such stockholder s basis in the fractional share and the amount of cash received; and

- such gain or loss will be a capital gain or loss, and generally will constitute long-term capital gain or loss if the stockholder s holding period for the stock surrendered is more than one year as of the closing date of the merger. Net capital gain (*i.e.*, the excess of net long-term capital gain over net short-term capital loss) will be subject to tax at reduced rates for non-corporate stockholders who receive cash. The deductibility of capital losses is subject to various limitations for corporate and non-corporate holders.

For purposes of the above discussion of the bases and holding periods for shares of Cornerstone s common stock and Critical Therapeutics common stock, stockholders who acquired different blocks of Cornerstone common stock at different times for different prices must calculate their gains and losses and holding periods separately for each identifiable block of such stock exchanged, converted, cancelled, or received in the merger.

The above discussion does not apply to Cornerstone s stockholders who properly perfect dissenters rights. Generally, a Cornerstone stockholder who perfects dissenters rights with respect to such stockholder s shares of Cornerstone common stock will recognize capital gain or loss equal to the difference between such stockholder s tax basis in such

shares and the amount of cash received in exchange for such shares.

Certain noncorporate Cornerstone stockholders may be subject to backup withholding, at a rate of 28% for 2008, on cash received pursuant to the merger. Backup withholding will not apply, however, to a Cornerstone stockholder who (1) furnishes a correct taxpayer identification number and certifies that the Cornerstone stockholder is not subject to backup withholding on IRS Form W-9 or a substantially similar form, (2) provides a certification of foreign status on an appropriate Form W-8 or successor form or (3) is otherwise exempt from backup withholding. If a Cornerstone stockholder does not provide a correct taxpayer

Table of Contents

identification number on IRS Form W-9 or a substantially similar form, the Cornerstone stockholder may be subject to penalties imposed by the IRS. Amounts withheld, if any, are generally not an additional tax and may be refunded or credited against the Cornerstone stockholder s federal income tax liability, provided that the Cornerstone stockholder furnishes the required information to the IRS.

**THE PRECEDING DISCUSSION IS INTENDED ONLY AS A SUMMARY OF THE MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER AND DOES NOT PURPORT TO BE A COMPLETE ANALYSIS OR DISCUSSION OF ALL OF THE MERGER S POTENTIAL TAX EFFECTS. CORNERSTONE STOCKHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE SPECIFIC TAX CONSEQUENCES TO THEM OF THE MERGER, INCLUDING TAX RETURN REPORTING REQUIREMENTS, AND THE APPLICABILITY AND EFFECT OF FEDERAL, STATE, LOCAL AND OTHER APPLICABLE TAX LAWS.**

**NASDAQ Listing**

Critical Therapeutics common stock is listed on The NASDAQ Capital Market under the symbol CRTX.

On June 13, 2008, NASDAQ approved the transfer of the listing of Critical Therapeutics common stock from The NASDAQ Global Market to The NASDAQ Capital Market effective at the opening of business on June 17, 2008. From July 2006 to June 16, 2008, Critical Therapeutics common stock traded on the NASDAQ Global Market. Prior to July 2006, Critical Therapeutics common stock traded on The NASDAQ National Market, the predecessor to The NASDAQ Global Market.

A condition to approval of the transfer of the listing of Critical Therapeutics common stock to The NASDAQ Capital Market was Critical Therapeutics satisfaction of The NASDAQ Capital Market s continued listing requirements, other than the $1.00 per share minimum bid price requirement. Separately, if Critical Therapeutics meets all of The NASDAQ Capital Market s initial listing requirements, other than the minimum bid price requirement, on October 20, 2008, which is the date that is 180 days following the date Critical Therapeutics received notification from NASDAQ that it failed to comply with the minimum bid price requirement, Critical Therapeutics will have the remainder of an additional 180 calendar day grace period while listed on The NASDAQ Capital Market to regain compliance with NASDAQ s minimum bid price requirement. There can be no assurance that on October 20, 2008 Critical Therapeutics will comply with The NASDAQ Capital Market s initial listing requirements, including The NASDAQ Capital Market s minimum stockholders equity requirement.

On August 13, 2008, Critical Therapeutics received notification from the NASDAQ Listing Qualification Department that, based on its stockholders equity of $1.2 million, as reported in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, and a market value of its common stock as of August 12, 2008 of $13.0 million, Critical Therapeutics does not comply with NASDAQ Marketplace Rule 4310(c)(3), which requires it to have, for continued listing on The NASDAQ Capital Market, a minimum of $2.5 million in stockholders equity or market value of listed securities of $35.0 million or $500,000 of net income from continuing operations for the most recently completed fiscal year or two of the three most recently completed fiscal years. As a result, the Listing Qualifications Staff is reviewing Critical Therapeutics eligibility for continued listing on The NASDAQ Capital Market. To facilitate the review, Critical Therapeutics provided to the Listing Qualifications Staff on September 3, 2008 a definitive plan, based on completing the proposed merger with Cornerstone, to achieve and sustain compliance with all NASDAQ Capital Market listing requirements. If after the conclusion of its review process the Listing Qualifications Staff determines that Critical Therapeutics plan does not adequately address the deficiencies noted, the Staff will provide written notice to Critical Therapeutics that its common stock will be delisted from The NASDAQ Capital Market. In such event, Critical Therapeutics may appeal the Staff s decision to a NASDAQ Listing Qualifications Panel.

Critical Therapeutics has filed an initial listing application with The NASDAQ Capital Market pursuant to NASDAQ s reverse merger rules for the re-listing of Critical Therapeutics common stock in connection with the merger and to effect the initial listing of Critical Therapeutics common stock issuable in connection with the merger or upon exercise of Cornerstone s outstanding stock options or warrants.

Table of Contents

**Anticipated Accounting Treatment**

The merger will be treated by Critical Therapeutics as a reverse merger under the purchase method of accounting in accordance with GAAP. For accounting purposes, Cornerstone is considered to be acquiring Critical Therapeutics in this transaction. Therefore, the aggregate consideration paid in connection with the merger, together with the direct costs of acquisition, will be allocated to Critical Therapeutics tangible and intangible assets and liabilities based on their fair market values. The assets and liabilities and results of operations of Critical Therapeutics will be consolidated into the results of operations of Cornerstone as of the effective time of the merger. These allocations will be based upon a valuation that has not yet been finalized.

**Appraisal Rights**

If the merger is completed, Cornerstone s stockholders are entitled to appraisal rights under Section 262 of the Delaware General Corporation Law, or Section 262, provided that they comply with the conditions established by Section 262. It is a condition to the obligation of Critical Therapeutics and the transitory subsidiary to complete the merger that holders of not more than 5% of Cornerstone s outstanding common stock exercise appraisal rights.

The following is a summary of the material terms regarding a Cornerstone stockholder s appraisal rights under Delaware law. It does not purport to be a complete discussion of all aspects of a stockholder s appraisal rights and is qualified in its entirety by reference to the text of the relevant provisions of Delaware law, which are attached to this proxy statement/prospectus as *Annex E*. Cornerstone s stockholders intending to exercise appraisal rights should carefully review *Annex E*. Failure to follow precisely any of the statutory procedures set forth in *Annex E* may result in a termination or waiver of these rights.

A record holder of shares of Cornerstone s common stock who makes the demand described below with respect to such shares, who continuously is the record holder of such shares through the effective time of the merger, who otherwise complies with the statutory requirements of Section 262 and who neither votes in favor of the merger nor consents thereto in writing will be entitled to an appraisal by the Delaware Court of Chancery, or the Delaware Court, of the fair value of his, her or its shares of Cornerstone s common stock in lieu of the consideration that such stockholder would otherwise be entitled to receive pursuant to the merger agreement. All references in this summary of appraisal rights to a stockholder or holders of shares of Cornerstone s common stock are to the record holder or holders of shares of Cornerstone s common stock. Except as set forth herein, Cornerstone s stockholders will not be entitled to appraisal rights in connection with the merger.

Under Section 262, where a merger is accomplished pursuant to Section 228 of the Delaware General Corporation Law, either a constituent corporation before the effective date of the merger, or the surviving or resulting corporation within 10 days after the effective date of the merger, must notify each stockholder of each constituent corporation entitled to appraisal rights of the approval of the merger and that appraisal rights are available to such stockholders and include in each such notice a copy of Section 262. This proxy statement/prospectus shall constitute such notice to the record holders of Cornerstone common stock.

Cornerstone s stockholders who desire to exercise their appraisal rights must satisfy all of the conditions of Section 262. Those conditions include the following:

> Holders of shares of Cornerstone common stock who desire to exercise their appraisal rights must, within 20 days after the date of mailing of this notice, demand in writing the appraisal of their shares.

The written demand for appraisal must be executed by or on behalf of the stockholder of record and must reasonably inform Cornerstone of the identity of the stockholder of record and that such stockholder intends thereby to demand appraisal of his, her or its Cornerstone common stock.

If the shares are owned of record by a person other than the beneficial owner, including a broker, fiduciary (such as a trustee, guardian or custodian), depositary or other nominee, such demand must be executed by or for the record owner. If the shares are owned by or for more than one person, as in a joint

Table of Contents

tenancy or tenancy in common, such demand must be executed by or for all joint owners. An authorized agent, including an agent for two or more joint owners, may execute the demand for appraisal for a stockholder of record. However, the agent must identify the record owner and expressly disclose the fact that, in exercising the demand, he is acting as agent for the record owner. A person having a beneficial interest in Cornerstone s common stock held of record in the name of another person, such as a broker or nominee, must act promptly to cause the record holder to follow the steps summarized herein in a timely manner to perfect whatever appraisal rights the beneficial owner may have.

A stockholder who elects to exercise appraisal rights should mail or deliver his, her or its written demand to Cornerstone at Cornerstone BioPharma Holdings, Inc., 2000 Regency Parkway, Suite 255, Cary, North Carolina 27518, Attention: Vice President, Finance.

Within ten days after the effective time of the merger, Cornerstone must provide notice of the effective time of the merger to all Cornerstone stockholders who have complied with Section 262 and have not voted in favor of the adoption of the merger agreement.

Within 120 days after the effective time of the merger, either Cornerstone or any stockholder who has complied with the required conditions of Section 262 may commence an appraisal proceeding by filing a petition in the Delaware Court, with a copy served on Cornerstone in the case of a petition filed by a stockholder, demanding a determination of the fair value of the shares of all dissenting stockholders. There is no present intent on the part of Cornerstone to file an appraisal petition, and stockholders seeking to exercise appraisal rights should not assume that Cornerstone will file such a petition or that Cornerstone will initiate any negotiations with respect to the fair value of such shares. Accordingly, holders of Cornerstone capital stock who desire to have their shares appraised should initiate any petitions necessary for the perfection of their appraisal rights within the time periods and in the manner prescribed in Section 262.

Within 120 days after the effective time of the merger, any stockholder who has satisfied the requirements of Section 262 will be entitled, upon written request, to receive from Cornerstone a statement setting forth the aggregate number of shares of Cornerstone common stock not voting in favor of the adoption of the merger agreement and with respect to which demands for appraisal were received by Cornerstone and the aggregate number of holders of such shares. A person who is the beneficial owner of shares of such stock held in a voting trust or by a nominee on behalf of such person may, in such person s own name, file a petition or request from the corporation the statement described in the previous sentence. Such statement must be mailed within 10 days after the stockholder s request has been received by Cornerstone or within 10 days after the expiration of the period for the delivery of demands as described above, whichever is later.

If a petition for an appraisal is timely filed and a copy thereof is served upon Cornerstone, Cornerstone will then be obligated, within 20 days after service, to file with the Register in Chancery a duly verified list containing the names and addresses of all stockholders who have demanded an appraisal of their shares and with whom agreements as to the value of their shares have not been reached. At the hearing on such petition, the Delaware Court will determine which stockholders are entitled to appraisal rights. The Delaware Court may require the stockholders who have demanded an appraisal for their shares and who hold stock represented by certificates to submit their certificates of stock to the Register in Chancery for notation thereon of the pendency of the appraisal proceedings; and if any stockholder fails to comply with such direction, the Delaware Court may dismiss the proceedings as to such stockholder. Where proceedings are not dismissed, the appraisal proceeding shall be conducted, as to the shares of Cornerstone capital stock owned by such stockholders, in accordance with the rules of the Delaware Court, including any rules specifically governing appraisal proceedings. Through such proceeding the Delaware Court shall determine the fair value of such shares exclusive of any element of value arising from the accomplishment or expectation of the merger, together with interest, if any, to be paid upon the amount determined to be the fair value.

Although the board of directors of Cornerstone believes that the merger consideration is fair, no representation is made as to the outcome of the appraisal of fair value as determined by the Delaware Court and stockholders should recognize that such an appraisal could result in a determination of a value higher or lower than, or the same as, the consideration they would receive pursuant to the merger agreement. Moreover, Cornerstone does

**Table of Contents**

not anticipate offering more than the merger consideration to any stockholder exercising appraisal rights and reserves the right to assert, in any appraisal proceeding, that, for purposes of Section 262, the fair value of a share of Cornerstone capital stock is less than the merger consideration. In determining fair value , the Delaware Court is required to take into account all relevant factors. In *Weinberger v. UOP, Inc.*, the Delaware Supreme Court discussed the factors that could be considered in determining fair value in an appraisal proceeding, stating that proof of value by any techniques or methods which are generally considered acceptable in the financial community and otherwise admissible in court should be considered and that [f]air price obviously requires consideration of all relevant factors involving the value of a company. The Delaware Supreme Court has stated that in making this determination of fair value the court must consider market value, asset value, dividends, earnings prospects, the nature of the enterprise and any other facts which could be ascertained as of the date of the merger which throw any light on future prospects of the merged corporation. Section 262 provides that fair value is to be exclusive of any element of value arising from the accomplishment or expectation of the merger. In *Cede & Co. v. Technicolor, Inc.*, the Delaware Supreme Court stated that such exclusion is a narrow exclusion [that] does not encompass known elements of value, but which rather applies only to the speculative elements of value arising from such accomplishment or expectation. In *Weinberger*, the Delaware Supreme Court construed Section 262 to mean that elements of future value, including the nature of the enterprise, which are known or susceptible of proof as of the date of the merger and not the product of speculation, may be considered.

The cost of the appraisal proceeding may be determined by the Delaware Court and taxed against the parties as the Delaware Court deems equitable in the circumstances. However, costs do not include attorneys and expert witness fees. Each dissenting stockholder is responsible for his or her attorneys and expert witness expenses, although, upon application of a dissenting stockholder, the Delaware Court may order that all or a portion of the expenses incurred by any dissenting stockholder in connection with the appraisal proceeding, including without limitation, reasonable attorneys fees and the fees and expenses of experts, be charged pro rata against the value of all shares of stock entitled to appraisal.

Any stockholder who has duly demanded appraisal in compliance with Section 262 will not, after the effective time of the merger, be entitled to vote for any purpose any shares subject to such demand or to receive payment of dividends or other distributions on such shares, except for dividends or distributions payable to stockholders of record at a date prior to the effective time of the merger.

At any time within 60 days after the effective time of the merger, any stockholder who has not commenced an appraisal proceeding or joined that proceeding as a named party will have the right to withdraw his, her or its demand for appraisal and to accept the terms offered in the merger agreement. After this period, a stockholder may withdraw his, her or its demand for appraisal and receive payment for his, her or its shares as provided in the merger agreement only with the consent of Cornerstone. If no petition for appraisal is filed with the Delaware Court within 120 days after the effective time of the merger, stockholders rights to appraisal will cease, and all holders of shares of Cornerstone common stock will be entitled to receive the consideration offered pursuant to the merger agreement. Inasmuch as Cornerstone has no obligation to file such a petition, and Cornerstone has no present intention to do so, any stockholder who desires a petition to be filed is advised to file it on a timely basis. Any stockholder may withdraw such stockholder s demand for appraisal by delivering to Cornerstone a written withdrawal of his, her or its demand for appraisal and acceptance of the merger consideration, except (i) that any such attempt to withdraw made more than 60 days after the effective time of the merger will require written approval of Cornerstone and (ii) that no appraisal proceeding in the Delaware Court shall be dismissed as to any stockholder without the approval of the Delaware Court, and such approval may be conditioned upon such terms as the Delaware Court deems just, provided, however, that this provision shall not affect the right of any stockholder who has not commenced an appraisal proceeding or joined that proceeding as a named party to withdraw such stockholder s demand for appraisal and to accept the terms offered upon the merger within 60 days.

Failure by any Cornerstone stockholder to comply fully with the procedures described above and set forth in *Annex E* to this proxy statement/prospectus may result in termination of such stockholder s appraisal rights.

Table of Contents

## THE MERGER AGREEMENT

*The following is a summary of the material terms of the merger agreement. A copy of the merger agreement is attached as Annex A to this proxy statement/prospectus and is incorporated by reference into this proxy statement/prospectus. The merger agreement has been attached to this proxy statement/prospectus to provide you with information regarding its terms. It is not intended to provide any other factual information about Critical Therapeutics, Cornerstone or the transitory subsidiary. The following description does not purport to be a complete discussion of all aspects of the merger agreement and is qualified in its entirety by reference to the merger agreement. You should refer to the full text of the merger agreement for details of the merger and the terms and conditions of the merger agreement.*

### General

Under the merger agreement, Cornerstone and the transitory subsidiary, a wholly owned subsidiary of Critical Therapeutics formed in connection with the merger, will merge, with Cornerstone surviving as a wholly owned subsidiary of Critical Therapeutics. After completion of the merger, Critical Therapeutics will operate under the name Cornerstone Therapeutics Inc. Immediately following the effective time of the merger, Cornerstone s stockholders will own approximately 70%, and Critical Therapeutics current stockholders will own approximately 30%, of Critical Therapeutics common stock, assuming the exchange or conversion prior to the merger of the outstanding principal amount of the Carolina Note into shares of Cornerstone s common stock and after giving effect to shares issuable pursuant to Cornerstone s outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics outstanding options and warrants.

The closing of the merger will occur no later than the second business day after the last of the conditions to the merger has been satisfied or waived, or at another time as Cornerstone and Critical Therapeutics agree. However, because the merger is subject to a number of conditions, neither Critical Therapeutics nor Cornerstone can predict exactly when the closing will occur or if it will occur at all.

### Merger Consideration

At the effective time of the merger, each share of Cornerstone s common stock will be converted into and exchanged for the right to receive a number of shares of Critical Therapeutics common stock equal to the product of 2.3333 multiplied by the quotient of 43,479,198, which was the number of outstanding shares of Critical Therapeutics common stock on April 30, 2008, divided by the number of shares of Cornerstone s common stock outstanding immediately prior to the effective time of the merger, assuming the exercise or conversion of all outstanding Cornerstone options and warrants, subject to adjustment for the reverse stock split of Critical Therapeutics common stock.

### Amendments to Critical Therapeutics Certificate of Incorporation

The merger agreement provides that Critical Therapeutics stockholders must approve, as a condition to closing the merger, an amendment to Critical Therapeutics certificate of incorporation to effect a reverse stock split of Critical Therapeutics common stock, which requires the affirmative vote of holders of a majority of the outstanding common stock on the record date for the special meeting. Upon the effectiveness of the amendment to Critical Therapeutics certificate of incorporation effecting the reverse stock split, the outstanding shares of Critical Therapeutics common stock will be reclassified and combined into a lesser number of shares such that one share of Critical Therapeutics common stock will be issued for a specified number of shares, which shall be greater than one and equal to or less

than 50, of outstanding Critical Therapeutics common stock, with the exact number within the range to be determined by Critical Therapeutics board of directors prior to the effective time of such amendment and publicly announced by Critical Therapeutics. As applicable NASDAQ initial listing standards require Critical Therapeutics to have, among other things, a $4.00 per share minimum bid price, the reverse stock split is necessary in order to consummate the merger.

Table of Contents

Stockholders of record of Critical Therapeutics common stock on the record date for the special meeting will also be asked to approve an amendment to Critical Therapeutics certificate of incorporation to change the name of the corporation from Critical Therapeutics to Cornerstone Therapeutics Inc. immediately following the consummation of the merger.

**Conditions to the Completion of the Merger**

Each party s obligation to complete the merger is subject to the satisfaction or waiver by each of the parties, at or prior to the merger, of various conditions, subject to specified exceptions, which include the following:

- the stockholders of Cornerstone must adopt the merger agreement, and the stockholders of Critical Therapeutics must approve the issuance of Critical Therapeutics common stock in the merger and the amendment to Critical Therapeutics certificate of incorporation to effect the reverse stock split and change the name of Critical Therapeutics to Cornerstone Therapeutics Inc. ;

- the waiting period (and any extensions thereof) applicable to the consummation of the merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and any other applicable law shall have expired or been terminated;

- all authorizations, consents, orders or approvals of, or declarations or filings with, or expirations of waiting periods imposed by, any governmental entity in connection with the merger and the consummation of the other transactions contemplated by the merger agreement have been filed, been obtained or occurred;

- the registration statement on Form S-4, of which this proxy statement/prospectus is a part, must have become effective under the Securities Act, no stop order suspending the effectiveness of the Form S-4 shall have been issued, and no proceeding for that purpose shall have been initiated or threatened in writing by the SEC;

- there must not have been issued any order, executive order, stay, decree, judgment or injunction (preliminary or permanent) or statute, rule or regulation which is in effect and which has the effect of making the consummation of the merger illegal or otherwise prohibiting consummation of the merger or the other transactions contemplated by the merger agreement; and

- there shall not be instituted or pending any action or proceeding by any governmental entity seeking to restrain, prohibit or otherwise interfere with the ownership or operation by Critical Therapeutics of Cornerstone or to compel Critical Therapeutics to dispose of or hold separate all or any portion of Cornerstone s business or assets or Critical Therapeutics business or assets, seeking to impose or confirm limitations on the ability of Critical Therapeutics effectively to exercise full rights of ownership of the shares of Cornerstone common stock or seeking to require divestiture by Critical Therapeutics of any shares of Cornerstone common stock.

In addition, each party s obligation to complete the merger is further subject to the satisfaction or waiver by that party of the following additional conditions:

- all representations and warranties of the other party in the merger agreement being true and correct on the date of the merger agreement and on the closing date of the merger, as if made on the closing date of the merger or, if such representations and warranties address matters as of a specific date, then as of that specific date, except, other than with respect to representations about such party s capitalization and required approvals of the merger agreement and related transactions, where the failure of these representations and warranties to be true and correct, disregarding any materiality qualifications, individually or in the aggregate, has not had and is not reasonably likely to have a material adverse effect on the party making the representations and warranties;

the other party to the merger agreement having performed in all material respects all obligations required to be performed by it on or before the closing of the merger;

Table of Contents

the other party having delivered the documents required under the merger agreement for the closing of the merger, including identified third party consents and certificates from specified officers;

no material adverse effect having occurred since the date of the merger agreement and be continuing with respect to the other party; and

the receipt of a written opinion from such party s tax counsel to the effect that the merger will be treated for U.S. federal income tax purposes as a reorganization within the meaning of Section 368(a) of the Code; provided that if a party s tax counsel does not render such an opinion, this condition will nonetheless be deemed satisfied if tax counsel for the other party renders such an opinion.

In addition, the obligation of Critical Therapeutics and the transitory subsidiary to complete the merger is further subject to the satisfaction or waiver of the following conditions:

the number of shares of Cornerstone common stock held as of the effective time of the merger that have not been voted in favor of the adoption of the merger agreement and with respect to which appraisal shall have been duly demanded and perfected in accordance with Delaware law shall not exceed 5% of the number of outstanding shares of Cornerstone s common stock as of the effective time of the merger;

the exchange or conversion of the outstanding principal amount under the Carolina Note for shares of Cornerstone s common stock; and

the delivery of fully executed copies of the voting agreements of Cornerstone s stockholders and noteholders.

In addition, the obligation of Cornerstone to complete the merger is further subject to the satisfaction or waiver of the following conditions:

the delivery of fully executed copies of the stockholder agreements of Critical Therapeutics stockholders;

NASDAQ shall have approved Critical Therapeutics application for initial inclusion on The NASDAQ Capital Market in connection with the listing of Critical Therapeutics common stock and the listing of shares of Critical Therapeutics issuable in connection with the merger or upon exercise of Cornerstone options and warrants; and

the availability of either ZYFLO CR or ZYFLO for purchase by third party wholesalers or retailers at all times from the date of the merger agreement through the closing of the merger, other than during any period that has not exceeded, and, as of the closing date of the merger, is not reasonably expected to exceed, 30 consecutive days.

A material adverse effect, with respect to a party, means any material adverse change, event, circumstance or development with respect to, or material adverse effect on, (i) the business, assets, liabilities, condition (financial or other), or results of operations of a party and its subsidiaries, taken as a whole, or (ii) the ability of a party and its subsidiaries to consummate the transactions contemplated by the merger agreement; provided, however, that any change or event caused by or resulting from the following shall not be deemed to be a material adverse effect (but, in the case of the first four bullets below, only to the extent that they do not have a materially disproportionate adverse effect on the party and its subsidiaries relative to other participants in the industries or markets in which they operate):

changes in prevailing economic or market conditions in the United States or any other jurisdiction in which a party and its subsidiaries have substantial business operations;

changes or events, after the date of the merger agreement, affecting the industries in which a party and its subsidiaries operate generally;

changes, after the date of the merger agreement, in generally accepted accounting principles or requirements applicable to the party and its subsidiaries;

Table of Contents

changes, after the date of the merger agreement, in laws, rules or regulations of general applicability or interpretations thereof by any court or governmental or regulatory authority;

the execution, delivery and performance of the merger agreement or the consummation of the transactions contemplated by the merger agreement or the announcement thereof;

any outbreak of major hostilities in which the United States is involved or any act of terrorism within the United States or directed against the facilities or citizens of the United States wherever located;

with respect to Critical Therapeutics, any issues or disruptions related to the manufacture of ZYFLO CR and its supply chain arising in connection with Critical Therapeutics investigation of certain batches of ZYFLO CR that are on a Quality Assurance Hold or failed to meet specifications;

with respect to Critical Therapeutics, the results of Mylan s strategic alternatives process for DEY and any impact on Critical Therapeutics co-promotion agreements with DEY; or

with respect to Critical Therapeutics, specified ordinary course operational exceptions as set forth in Critical Therapeutics disclosure schedule to the merger agreement.

**No Solicitation**

Each of Cornerstone and Critical Therapeutics agreed that, except as described below, neither Cornerstone nor Critical Therapeutics shall, nor shall either of them authorize or permit any of their or their respective subsidiaries subsidiaries or any of their or their subsidiaries respective directors, officers, employees, investment bankers, attorneys, accountants or other advisors or representatives to, directly or indirectly:

solicit, initiate, encourage or take any other action designed to facilitate any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, any acquisition proposal, as defined below; or

enter into, continue or otherwise participate in any discussions or negotiations regarding, furnish to any person any information with respect to, assist or participate in any effort or attempt by any person with respect to, or otherwise cooperate in any way with, any acquisition proposal.

An acquisition proposal means, with respect to any party, any inquiry, proposal or offer from any person relating to, in a single transaction or series of related transactions, any (i) acquisition of assets of such party and its subsidiaries, excluding sales of assets in the ordinary course of business consistent with past practice, equal to 10% or more of such party s consolidated assets or to which 10% or more of such party s revenues or earnings on a consolidated basis are attributable, (ii) acquisition of 10% or more of such party s outstanding common stock, (iii) tender offer or exchange offer that if consummated would result in any person beneficially owning 10% or more of such party s outstanding common stock, (iv) merger, consolidation, share exchange, business combination, recapitalization, liquidation, dissolution or similar transaction involving such party or any of its subsidiaries or (v) any combination of the foregoing types of transactions if the sum of the percentage of consolidated assets, consolidated revenues or earnings and common stock involved is 10% or more, in each case, other than the merger.

However, if at any time prior to the approval of the issuance of the shares of Critical Therapeutics common stock in the merger at the special meeting, Critical Therapeutics receives a written acquisition proposal from any person or group of persons that did not result from a breach of Critical Therapeutics obligations described above, (i) Critical

Therapeutics may contact such person or group of persons to clarify the terms and conditions thereof and (ii) if Critical Therapeutics board of directors, or any committee thereof, determines in good faith, after consultation with outside legal counsel and a nationally recognized financial advisor, that such acquisition proposal constitutes or could reasonably be expected to lead to a superior proposal, as defined below, then Critical Therapeutics and its representatives may, subject to compliance with the merger agreement (x) furnish information with respect to Critical Therapeutics to the person making such acquisition proposal and its representatives pursuant to a customary confidentiality agreement not less restrictive of the other party than the confidentiality agreement entered into between Critical Therapeutics and Cornerstone and

Table of Contents

(y) participate in discussions or negotiations with such person and its representatives regarding any superior proposal.

A superior proposal means, with respect to Critical Therapeutics, any unsolicited, bona fide written acquisition proposal on terms that Critical Therapeutics board of directors determines in its good faith judgment to be (i) materially more favorable to the stockholders of Critical Therapeutics than the transactions contemplated by the merger agreement, taking into account all the terms and conditions of such proposal (including the likelihood and timing of consummation thereof) and the merger agreement (including any written proposal by either party to amend the terms of the merger agreement in response to such acquisition proposal or otherwise) and after consultation with outside legal counsel and a nationally recognized financial advisor, and (ii) reasonably capable of being completed on the terms proposed, taking into account all financial, regulatory, legal and other aspects of such proposal; provided, however, that no acquisition proposal shall be deemed to be a superior proposal if any financing required to consummate the acquisition proposal is not fully and irrevocably committed; and provided, further, that for purposes of the definition of superior proposal, the references to 10% in the definition of acquisition proposal shall be deemed to be references to 50% .

**Change in Recommendation**

The merger agreement provides that neither Critical Therapeutics board of directors nor Cornerstone s board of directors shall (i) except in the manner permitted with respect to an acquisition proposal, withdraw or modify, or publicly propose to withdraw or modify, in a manner adverse to the other party, its approval or recommendation with respect to the Critical Therapeutics proposals to issue shares of common stock in connection with the merger, effect the reverse stock split and change the name of Critical Therapeutics to Cornerstone Therapeutics Inc. or the adoption of the merger agreement by Cornerstone s stockholders, as the case may be; (ii) cause or permit such party to enter into any letter of intent, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement or similar agreement constituting or relating to any acquisition proposal, other than, with respect to Critical Therapeutics, a confidentiality agreement entered into in the circumstances permitted by the merger agreement; or (iii) adopt, approve or recommend, or propose to adopt, approve or recommend, any acquisition proposal.

Notwithstanding the foregoing, Critical Therapeutics board of directors may withdraw or modify its recommendation with respect to its proposals to issue shares of common stock in connection with the merger, effect the reverse stock split and change the name of Critical Therapeutics to Cornerstone Therapeutics Inc. if Critical Therapeutics board of directors determines in good faith after consultation with outside counsel that its fiduciary obligations require it to do so, but only at a time that is prior to the approval of the issuance of shares of Critical Therapeutics common stock at the special meeting and after the fifth business day following receipt by Cornerstone of written notice advising it that Critical Therapeutics board of directors desires to withdraw or modify the recommendation and, if such withdrawal is due to the existence of an acquisition proposal, specifying the material terms and conditions of such acquisition proposal and identifying the person making such acquisition proposal.

**Meeting of Critical Therapeutics Stockholders**

Critical Therapeutics is obligated under the merger agreement to call, give notice of and hold the special meeting for purposes of approving the issuance of shares of Critical Therapeutics common stock in the merger, approving the amendment to Critical Therapeutics certificate of incorporation to effect the reverse stock split and the amendment to Critical Therapeutics certificate of incorporation to change the name of Critical Therapeutics to Cornerstone Therapeutics Inc.

The obligation to call, give notice of and hold the special meeting remains applicable even if Critical Therapeutics accepts or recommends a superior proposal, unless Cornerstone terminates the merger agreement.

Table of Contents

**Covenants; Conduct of Business Pending the Merger**

Cornerstone agreed that it will, and will cause each of its subsidiaries to, act and carry on its business in the usual, regular and ordinary course in substantially the same manner as previously conducted, pay its debts and taxes and perform its other obligations when due, comply with applicable laws, rules and regulations, and use commercially reasonable efforts, consistent with past practices, to maintain and preserve its and each of its subsidiaries business organization, assets and properties, keep available the services of its present officers and key employees and preserve its advantageous business relationships with customers, strategic partners, suppliers, distributors and others having business dealings with it. Cornerstone also specifically agreed that, subject to specified exceptions, without the consent of Critical Therapeutics, it would not, during the period prior to the effective time of the merger:

declare, set aside or pay any dividends or make any other distributions in respect of any shares of its capital stock or repurchase any securities (other than dividends and distributions by a direct or indirect wholly owned subsidiary of Cornerstone), split, combine or reclassify its capital stock or purchase, redeem or otherwise acquire shares of its capital stock or any rights, warrants or options other than from former employees, directors and consultants;

issue, deliver, sell, grant, pledge or otherwise dispose of or encumber any securities, including options and warrants, other than the issuance of shares of Cornerstone common stock upon the exercise of options and warrants;

amend its certificate of incorporation, bylaws or other comparable charter or organizational documents;

except for purchases of inventory in the ordinary course of business consistent with past practice, acquire (i) by merging or consolidating with, or by purchasing all or a substantial portion of the assets or any stock of, or by any other manner, any business or any corporation, partnership, joint venture, limited liability company, association or other business organization or division thereof or (ii) any assets that are material, in the aggregate, to Cornerstone and its subsidiaries, taken as a whole;

except in the ordinary course of business consistent with past practice, sell, lease, license, pledge, or otherwise dispose of or encumber any properties or assets of Cornerstone or of any of its subsidiaries;

sell, dispose of or otherwise transfer any assets material to Cornerstone and its subsidiaries;

adopt or implement any stockholder rights plan;

enter into an agreement with respect to any merger, consolidation, liquidation or business combination, or any acquisition or disposition of all or substantially all of the assets or securities of Cornerstone or any of its subsidiaries;

(i) incur or permit to exist any indebtedness other than indebtedness that existed as of December 31, 2007 as reflected on Cornerstone s balance sheet or pursuant to Cornerstone s $4.0 million line of credit with Paragon Commercial Bank in the ordinary course of business consistent with past practice or guarantee any such indebtedness of another person, (ii) issue, sell or amend any debt securities or warrants or other rights to acquire any debt securities of Cornerstone or any of its subsidiaries, guarantee any debt securities of another person, enter into any keep well or other agreement to maintain any financial statement condition of another person or enter into any arrangement having the economic effect of any of the foregoing, (iii) make any loans,

advances (other than routine advances to employees of Cornerstone in the ordinary course of business consistent with past practice) or capital contributions to, or investment in, any other person, other than Cornerstone or any of its direct or indirect wholly owned subsidiaries or (iv) enter into any hedging agreement or other financial agreement or arrangement designed to protect Cornerstone or its subsidiaries against fluctuations in commodities prices or exchange rates;

make any capital expenditures or other expenditures with respect to property, plant or equipment in excess of $50,000 in the aggregate for Cornerstone and its subsidiaries;

Table of Contents

make any changes in accounting methods, principles or practices, except insofar as may have been required by the SEC or a change in GAAP, or, except as so required, change any assumption underlying, or method of calculating, any bad debt, contingency or other reserve;

modify, amend or terminate any material contract or agreement to which Cornerstone or any of its subsidiaries is party, or knowingly waive, release or assign any material rights or claims, except in the ordinary course of business consistent with past practice or, to the extent subject to reserves reflected on Cornerstone s balance sheet as of December 31, 2007, in accordance with GAAP;

(i) except in the ordinary course of business consistent with past practice, enter into any material contract or agreement relating to the rendering of services or the distribution, sale or marketing by third parties of the products of, or products licensed by, Cornerstone or any of its subsidiaries or (ii) license any material intellectual property to or from any third party;

except as required to comply with applicable law or agreements, plans or arrangements existing on the date of the merger agreement, (i) take any action with respect to, adopt, enter into, terminate or amend any employment, severance or similar agreement or benefit plan for the benefit or welfare of any current or former director, officer, employee or consultant or any collective bargaining agreement, (ii) increase in any material respect the compensation or fringe benefits of, or pay any bonus to, any director, officer, employee or consultant (except for annual increases of the salaries of non-officer employees in the ordinary course), (iii) amend or accelerate the payment, right to payment or vesting of any compensation or benefits, including any outstanding Cornerstone stock options or restricted stock awards, (iv) pay any material benefit not provided for as of the date of the merger agreement under any benefit plan, (v) grant any awards under any bonus, incentive, performance or other compensation plan or arrangement or benefit plan (including the grant of stock options, stock appreciation rights, stock based or stock related awards, performance units or restricted stock, or the removal of existing restrictions in any benefit plans or agreements or awards made thereunder), except for the grant of options to purchase Cornerstone common stock to new hires, which grants shall not exceed 100,000 shares in the aggregate and 5,000 shares to any one person, and which option grants shall have an exercise price equal to the fair market value of Cornerstone common stock on the date of grant (determined in a manner consistent with Cornerstone s existing practice for establishing fair market value for option grants and which option grants shall otherwise be upon Cornerstone s customary terms) or (vi) take any action other than in the ordinary course of business consistent with past practice to fund or in any other way secure the payment of compensation or benefits under any employee plan, agreement, contract or arrangement or benefit plan;

make or rescind any material tax election, settle or compromise any material tax liability or amend any tax return except as required by applicable law;

commence any offering of shares of Cornerstone common stock pursuant to any employee stock purchase plan, permit any employee to enroll in any employee stock purchase plan or allow any participant in an employee stock purchase plan to increase the current level of such participant s payroll deductions thereunder;

initiate, compromise or settle any material litigation or arbitration proceeding;

open or close any facility or office;

fail to use commercially reasonable efforts to maintain insurance at levels substantially comparable to levels existing as of the date of the merger agreement;

fail to pay accounts payable and other obligations in the ordinary course of business consistent with past practice;

fail to use commercially reasonable efforts to maintain inventory levels in the sales channel to ensure product availability to meet expected patient demand; provided, however, that the inventory level of any individual product in the sales channel shall not exceed the aggregate sales for the preceding three

Table of Contents

months for such product, as measured by industry standard third party data sources, such as IMS Health, National Prescription Audit or the like; or

agree or commit to take any of these restricted actions.

Critical Therapeutics agreed that it will, and will cause each of its subsidiaries to, act and carry on its business in the usual, regular and ordinary course in substantially the same manner as previously conducted, pay its debts and taxes and perform its other obligations when due, comply with applicable laws, rules and regulations, and use commercially reasonable efforts, consistent with past practices, to maintain and preserve its and each of its subsidiaries business organization, assets and properties, keep available the services of its present officers and key employees and preserve its advantageous business relationships with customers, strategic partners, suppliers, distributors and others having business dealings with it. Critical Therapeutics also specifically agreed that, subject to limited exceptions, without the consent of Cornerstone, it would not, during the period prior to the effective time of the merger:

declare, set aside or pay any dividends or make any other distributions in respect of any shares of its capital stock or repurchase any securities (other than dividends and distributions by a direct or indirect wholly owned subsidiary of Critical Therapeutics), with the exception of the reverse stock split, split, combine or reclassify its capital stock or purchase, redeem or otherwise acquire shares of its capital stock or any rights, warrants or options other than from former employees, directors and consultants;

issue, deliver, sell, grant, pledge or otherwise dispose of or encumber any securities, including options and warrants, other than the issuance of shares of Critical Therapeutics common stock upon exercise of options and warrants;

amend its certificate of incorporation, bylaws or other comparable charter or organizational documents, except to the extent necessary to carry into effect the reverse stock split and the change of the name of Critical Therapeutics to Cornerstone Therapeutics Inc. ;

except for purchases of inventory in the ordinary course of business consistent with past practice, acquire (i) by merging or consolidating with, or by purchasing all or a substantial portion of the assets or any stock of, or by any other manner, any business or any corporation, partnership, joint venture, limited liability company, association or other business organization or division thereof or (ii) any assets that are material, in the aggregate, to Critical Therapeutics and its subsidiaries, taken as a whole;

except in the ordinary course of business consistent with past practice, sell, lease, license, pledge, or otherwise dispose of or encumber any properties or assets;

sell, dispose of or otherwise transfer any assets material to Critical Therapeutics;

adopt or implement any stockholder rights plan;

except for a confidentiality agreement as permitted in connection with an acquisition proposal, enter into an agreement with respect to any merger, consolidation, liquidation or business combination, or any acquisition or disposition of all or substantially all of the assets or securities of Critical Therapeutics;

(i) incur or permit to exist any indebtedness for borrowed money or guarantee any such indebtedness of another person, (ii) issue, sell or amend any debt securities or warrants or other rights to acquire any debt securities of Critical Therapeutics, guarantee any debt securities of another person, enter into any keep well or other agreement to maintain any financial statement condition of another person or enter into any arrangement

having the economic effect of any of the foregoing, (iii) make any loans, advances (other than routine advances to employees of Critical Therapeutics in the ordinary course of business consistent with past practice) or capital contributions to, or investment in, any other person, other than Critical Therapeutics or any of its direct or indirect wholly owned subsidiaries or (iv) enter into any hedging agreement or other financial agreement or arrangement designed to protect Critical Therapeutics or its subsidiaries against fluctuations in commodities prices or exchange rates;

Table of Contents

make any capital expenditures or other expenditures with respect to property, plant or equipment in excess of $50,000 in the aggregate for Critical Therapeutics and its subsidiaries, taken as a whole, other than as set forth in Critical Therapeutics budget for capital expenditures made available to Cornerstone or specific capital expenditures disclosed and set forth on Critical Therapeutics disclosure schedule;

make any changes in accounting methods, principles or practices, except insofar as may have been required by the SEC or a change in GAAP or, except as so required, change any assumption underlying, or method of calculating, any bad debt, contingency or other reserve;

modify, amend or terminate any material contract or agreement to which Critical Therapeutics is party, or knowingly waive, release or assign any material rights or claims (including any write-off or other compromise of any accounts receivable of Critical Therapeutics or any of its subsidiaries), except in the ordinary course of business consistent with past practice or, to the extent subject to reserves reflected on the Critical Therapeutics balance sheet as of December 31, 2007, in accordance with GAAP;

(i) except in the ordinary course of business consistent with past practice, enter into any material contract or agreement relating to the rendering of services or the distribution, sale or marketing by third parties of the products of, or products licensed by, Critical Therapeutics or (ii) license any material intellectual property to or from any third party;

except as required to comply with applicable law or agreements, plans or arrangements existing on the date of the merger agreement, (i) take any action with respect to, adopt, enter into, terminate or amend any employment, severance or similar agreement or benefit plan for the benefit or welfare of any current or former director, officer, employee or consultant or any collective bargaining agreement, (ii) increase in any material respect the compensation or fringe benefits of, or pay any bonus to, any director, officer, employee or consultant (except for annual increases of the salaries of non-officer employees in the ordinary course), (iii) amend or accelerate the payment, right to payment or vesting of any compensation or benefits, including any outstanding Critical Therapeutics stock option or restricted stock awards, (iv) pay any material benefit not provided for as of the date of the merger agreement under any benefit plan, (v) grant any awards under any bonus, incentive, performance or other compensation plan or arrangement or benefit plan (including the grant of stock options, stock appreciation rights, stock based or stock related awards, performance units or restricted stock, or the removal of existing restrictions in any benefit plans or agreements or awards made thereunder), except for the grant of options to purchase Critical Therapeutics common stock to new hires, which grants shall not exceed 100,000 shares in the aggregate and 5,000 shares to any one person, and which option grants shall have an exercise price equal to the fair market value of Critical Therapeutics common stock on the date of grant (determined in a manner consistent with Critical Therapeutics existing practice for establishing fair market value for option grants and which option grants shall otherwise be upon Critical Therapeutics customary terms) or (vi) take any action other than in the ordinary course of business consistent with past practice to fund or in any other way secure the payment of compensation or benefits under any employee plan, agreement, contract or arrangement or benefit plan;

make or rescind any material tax election, settle or compromise any material tax liability or amend any tax return except as required by applicable law;

commence any offering of shares of Critical Therapeutics common stock pursuant to any employee stock purchase plan, permit any employee to enroll in any employee stock purchase plan or allow any participant in an employee stock purchase plan to increase the current level of such participant s payroll deductions thereunder;

initiate, compromise or settle any material litigation or arbitration proceeding;

open or close any facility or office;

fail to use commercially reasonable efforts to maintain insurance at levels substantially comparable to levels existing as of the date of the merger agreement;

Table of Contents

fail to pay accounts payable and other obligations in the ordinary course of business consistent with past practice;

fail to use commercially reasonable efforts to maintain inventory levels in the sales channel to ensure product availability to meet expected patient demand; provided, however, that the inventory level of any individual product in the sales channel shall not exceed the aggregate sales for the preceding three months for such product, as measured by industry standard third party data sources, such as IMS Health, National Prescription Audit or the like;

fail to appropriately adjust any Critical Therapeutics stock options or warrants so that the exercise prices and number of shares issuable upon exercise provide the holder the same economic benefit as existed immediately prior to the reverse stock split; or

agree or commit to take any of these restricted actions.

**Other Agreements**

Each of Cornerstone and Critical Therapeutics has agreed to use its commercially reasonable efforts to:

take all actions necessary to complete the merger;

promptly file or otherwise submit all applications, notices, reports and other documents reasonably required to be filed with a governmental entity with respect to the merger;

obtain any approvals under applicable antitrust laws and lift any injunction prohibiting the merger or other transactions contemplated by the merger agreement under antitrust laws;

obtain all consents, approvals or waivers reasonably required in connection with the transactions contemplated by the merger agreement;

consult and agree with each other about any public statement or press release either will make concerning the merger; and

cause the merger to qualify as a reorganization within the meaning of Section 368(a) of the Code.

Cornerstone and Critical Therapeutics also have agreed:

that Critical Therapeutics will, in consultation with Cornerstone, file an application for initial inclusion on The NASDAQ Capital Market in connection with the listing of Critical Therapeutics common stock in connection with NASDAQ s reverse merger rules and to effect the listing of Critical Therapeutics common stock issuable in connection with the merger or upon exercise of Cornerstone s outstanding stock options or warrants;

to provide reasonable access to information to the other party and to coordinate with the other in preparing and exchanging information and to promptly provide the other with copies of all filings or submissions made in connection with the merger;

that for a period of six years after the merger, the combined company will indemnify each of the directors and officers of Critical Therapeutics to the fullest extent permitted by law and will maintain directors and officers

liability insurance for Critical Therapeutics directors and officers;

to use reasonable efforts to consult and agree with each other about any statement or materials sent to employees; and

to notify the other party of any event, the occurrence of which would be reasonably likely to cause a representation or warranty in the merger agreement to be inaccurate or untrue or any material failure of a party to comply with or satisfy a covenant or condition in the merger agreement.

Table of Contents

**Termination**

The merger agreement may be terminated at any time before the completion of the merger, whether before or after the required Cornerstone stockholder approval of the merger has been obtained, as set forth below:

by mutual written consent of Cornerstone and Critical Therapeutics;

by either Cornerstone or Critical Therapeutics if the merger has not been completed by November 30, 2008, but this right to terminate the merger agreement will not be available to any party whose failure to fulfill any obligation under the merger agreement has been a principal cause of or resulted in the failure of the merger to be completed by such date;

by either Cornerstone or Critical Therapeutics if a governmental entity has issued a nonappealable final order, decree or ruling or taken any other nonappealable final action that permanently restrains, enjoins or otherwise prohibits the merger;

by either Cornerstone or Critical Therapeutics if Critical Therapeutics stockholders do not approve each of the proposals presented at the special meeting at which a vote on such proposals is taken, but this right to terminate the merger agreement will not be available (i) to a party if such party is in breach of or has failed to fulfill its obligations under the merger agreement or (ii) to Critical Therapeutics if the failure to obtain the requisite vote was caused by a breach by any party other than Cornerstone of the stockholder agreements entered into with Critical Therapeutics stockholders in connection with the merger;

by Critical Therapeutics if (i) Cornerstone s board of directors fails to recommend that Cornerstone s stockholders vote to approve the merger agreement and the merger or withdraws or modifies its recommendation, (ii) after the receipt by Cornerstone of an acquisition proposal, Cornerstone s board of directors fails to reconfirm its recommendation of the merger agreement or the merger within five business days after a request by Critical Therapeutics for such reconfirmation, (iii) Cornerstone s board of directors approves or recommends to Cornerstone s stockholders any acquisition proposal, (iv) a tender offer or exchange offer for outstanding shares of Cornerstone s common stock is commenced and Cornerstone s board of directors recommends that Cornerstone s stockholders tender their shares in such offer or fails to recommend against acceptance of such offer within 10 business days following commencement of such offer or (v) Cornerstone breaches its non-solicitation obligations or stockholder covenants (each of clauses (i) through (v) above is referred to herein as a Cornerstone Triggering Event );

by Cornerstone if (i) Critical Therapeutics board of directors fails to recommend that Critical Therapeutics stockholders vote for the proposals presented at the special meeting or withdraws or modifies its recommendation, (ii) after the receipt by Critical Therapeutics of an acquisition proposal, Critical Therapeutics board of directors fails to reconfirm its recommendation of the merger agreement or the merger within five business days after a request by Cornerstone for such reconfirmation, (iii) Critical Therapeutics board of directors approves or recommends to Critical Therapeutics stockholders any acquisition proposal, (iv) a tender offer or exchange offer for outstanding shares of Critical Therapeutics common stock is commenced (other than by Cornerstone or its affiliates) and Critical Therapeutics board of directors recommends that Critical Therapeutics stockholders tender their shares in such offer or fails to recommend against acceptance of such offer within 10 business days following commencement of such offer, (v) Critical Therapeutics breaches its non-solicitation obligations or stockholder covenants or (vi) Critical Therapeutics fails to hold the special meeting of its stockholders by November 28, 2008 (each of clauses (i) through (vi) above is referred to herein

as a Critical Therapeutics Triggering Event );

by either Cornerstone or Critical Therapeutics if there has been a breach of or failure to perform any representation, warranty, covenant or agreement set forth in the merger agreement by the other party which breach would cause conditions to the closing of the merger not to be satisfied, and such failure or breach with respect to any such representation, warranty, covenant or agreement cannot be cured or, if curable, continues unremedied for a period of 30 days after receipt of written notice from the non-

Table of Contents

breaching party of the occurrence of such failure or breach, provided that in no event shall such 30 day period extend beyond November 26, 2008, which written notice must be provided promptly following such time as such party obtains actual knowledge of such failure or breach (the events above are referred to herein as an Uncured Breach );

by Critical Therapeutics if Cornerstone does not obtain stockholder approval of the merger agreement by delivery of the written consents of Cornerstone s stockholders by 5:00 p.m., New York City time, on May 2, 2008; or

by Critical Therapeutics if (i) Cornerstone has not engaged a new independent registered public accounting firm by May 22, 2008, (ii) the audit of Cornerstone s financial statements as of the end of and for each of the last three fiscal years and a review in accordance with Statement on Auditing Standards No. 100 of the unaudited financial statements required to be included in this Form S-4 by Cornerstone s new auditors has not been completed by August 31, 2008 or (iii) the audit performed by Cornerstone s new auditors reflects a material adverse change with respect to the assets, liabilities, capitalization, financial condition or results of operations of Cornerstone as compared to the financial statements delivered by Cornerstone for such periods prior to the execution of the merger agreement (each of clauses (i) through (iii) above is referred to herein as the Cornerstone Audit Requirements ).

**Termination Fee**

***Fee Payable by Critical Therapeutics***

Critical Therapeutics must pay Cornerstone a termination fee of $1.0 million if the merger agreement is terminated (i) by Cornerstone because the merger has not occurred by November 30, 2008 if the merger has not occurred by such date due to the failure of Critical Therapeutics to satisfy closing conditions relating to approval by Critical Therapeutics stockholders of the proposals presented at the special meeting, the fulfillment of Critical Therapeutics obligations under the merger agreement or delivery of the stockholder agreements entered into with Critical Therapeutics stockholders, (ii) by Cornerstone or Critical Therapeutics because Critical Therapeutics stockholders failed to approve the proposals presented at the special meeting if at or prior to the time of such failure an acquisition proposal relating to Critical Therapeutics was announced and was not abandoned or withdrawn or (iii) by Cornerstone because of the occurrence of a Critical Therapeutics Triggering Event or an Uncured Breach by Critical Therapeutics.

In addition, Critical Therapeutics must pay Cornerstone up to $150,000 as reimbursement for expenses incurred in connection with the merger if the merger agreement is terminated (i) by either Cornerstone or Critical Therapeutics because the merger has not occurred by November 30, 2008 if the merger has not occurred by such date due to the failure of Critical Therapeutics to satisfy closing conditions relating to approval by Critical Therapeutics stockholders of the proposals presented at the special meeting, the accuracy of Critical Therapeutics representations and warranties, the fulfillment of Critical Therapeutics obligations under the merger agreement or delivery of the stockholder agreements of Critical Therapeutics stockholders, (ii) by either Cornerstone or Critical Therapeutics because Critical Therapeutics stockholders failed to approve the proposals presented at the special meeting or (iii) by Cornerstone because of the occurrence of a Critical Therapeutics Triggering Event or an Uncured Breach by Critical Therapeutics.

***Fee Payable by Cornerstone***

Cornerstone must pay Critical Therapeutics a termination fee of $1.0 million if the merger agreement is terminated by Critical Therapeutics because (i) the merger has not occurred by November 30, 2008 if the merger has not occurred by such date due to the failure of Cornerstone to satisfy closing conditions relating to approval of the merger agreement and the merger by Cornerstone s stockholders, the fulfillment of Cornerstone s obligations under the merger agreement,

the conversion or exchange of the outstanding principal amount of the Carolina Note into shares of Cornerstone s common stock, delivery of the noteholder agreement entered into with Carolina Pharmaceuticals or delivery of the stockholder agreements entered into with Cornerstone s stockholders, (ii) a Cornerstone Triggering Event or an Uncured Breach by Cornerstone has occurred, (iii) Cornerstone has not obtained stockholder approval of the written consents of Cornerstone s

Table of Contents

stockholders by 5:00 p.m., New York City time, on May 2, 2008 or (iv) Cornerstone s failure to meet the Cornerstone Audit Requirements.

In addition, Cornerstone must pay Critical Therapeutics up to $100,000 as reimbursement for expenses incurred in connection with the merger if the merger agreement is terminated (i) by either Cornerstone or Critical Therapeutics because the merger has not occurred by November 30, 2008 if the merger has not occurred by such date due to the failure of Cornerstone to satisfy closing conditions relating to approval of the merger agreement and the merger by Cornerstone s stockholders, the accuracy of Cornerstone s representations and warranties, the fulfillment of Cornerstone s obligations under the merger agreement, the conversion or exchange of the outstanding principal amount of the Carolina Note into shares of Cornerstone s common stock, delivery of the noteholder agreement entered into with Carolina Pharmaceuticals or delivery of the stockholder agreements of Cornerstone s stockholders or (ii) by Critical Therapeutics due to (A) a Cornerstone Triggering Event, (B) an Uncured Breach by Cornerstone, (C) Cornerstone s failure to obtain approval by its stockholders of the merger agreement and merger or (D) Cornerstone s failure to meet the Cornerstone Audit Requirements.

**Representations and Warranties**

The merger agreement contains customary representations and warranties of Critical Therapeutics, Cornerstone and the transitory subsidiary for a transaction of this type. Critical Therapeutics representations and warranties are qualified by its disclosure schedules and, in some cases, by Critical Therapeutics SEC reports. Cornerstone s representations and warranties are qualified by its disclosure schedules. The representations and warranties in the merger agreement relate to, among other things:

- corporate organization, standing and power;
- capital structure;
- subsidiaries;
- authority, no conflict, required filings and consents;
- financial statements and, with respect to Critical Therapeutics, documents filed with the SEC and the accuracy of information contained in those documents;
- any undisclosed liabilities;
- any material changes or events;
- tax matters;
- owned and leased real property;
- intellectual property;
- agreements, contracts and commitments;
- litigation matters;
- environmental matters;

employment benefit plans;

employee and labor matters;

compliance with laws

permits and regulatory matters;

agreements with employees;

insurance matters;

with respect to Critical Therapeutics, the opinion of Critical Therapeutics financial advisor;

Table of Contents

with respect to Critical Therapeutics, the inapplicability of the provisions of Section 203 of the Delaware General Corporation Law to the merger;

the absence of any existing discussions regarding an acquisition proposal;

controls and procedures, certifications and other matters related to the Sarbanes-Oxley Act;

with respect to Cornerstone, transactions with affiliates;

brokers fees and expenses;

with respect to Cornerstone, books and records; and

with respect to Critical Therapeutics, the operations of the transitory subsidiary.

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the merger, but their accuracy forms the basis of one of the conditions to the obligations of Cornerstone and Critical Therapeutics to complete the merger.

**Amendment**

The merger agreement may be amended by the parties by action taken or authorized by their respective board of directors, at any time before or after approval of the matters presented in connection with the merger by the stockholders of any of the parties, but, after any such approval, no amendment shall be made which by law requires further approval of such stockholders without such further approval.

On August 7, 2008, the parties entered into an amendment to the merger agreement to correct an erroneous reference in the merger agreement to the product Tussionex® being owned by Cornerstone. The merger agreement should have referred to Cornerstone s extended-release antihistamine and hydrocodone cough suppressant product candidates that, if approved by the FDA, will compete with Tussionex in the hydrocodone cough suppressant market. The foregoing summary of this amendment is not complete and is qualified in its entirety by reference to the full text of the amendment, which is included in *Annex A* to this proxy statement/prospectus and is incorporated by reference herein.

**Cornerstone Operating Company Guarantee**

Cornerstone BioPharma, Inc., a Nevada corporation and a wholly owned subsidiary of Cornerstone, is guaranteeing the performance by Cornerstone of its obligations under the merger agreement and is jointly and severally liable for payment of any termination fee or expenses owing to Critical Therapeutics under the merger agreement.

Table of Contents

## AGREEMENTS RELATED TO THE MERGER

### Cornerstone Stockholder Agreements

In connection with the execution of the merger agreement, holders of approximately 81% of the shares of Cornerstone s outstanding common stock have entered into agreements with Critical Therapeutics that provide, among other things, that the stockholders will vote in favor of adoption of the merger agreement and grant to Critical Therapeutics an irrevocable proxy to vote all of such stockholders shares of Cornerstone common stock in favor of adoption of the merger agreement and against any proposal made in opposition to, or in competition with, the proposal to adopt the merger agreement. In addition, these Cornerstone stockholders have agreed not to transfer or otherwise dispose of any shares of Critical Therapeutics common stock that they receive in the merger for 180 days after the effective time of the merger. In addition, certain directors and officers of Cornerstone that hold options to acquire Cornerstone s common stock have entered into identical stockholder agreements that would apply to any Cornerstone stock beneficially owned at the effective time of the merger.

The Cornerstone stockholders and option holders that entered into the stockholder agreements with Critical Therapeutics are Cornerstone BioPharma Holdings, Ltd., Craig A. Collard, Craig Collard Irrevocable Trust, James V. Baker, Chenyqua Baldwin, Lutz Family Limited Partnership, Alastair McEwan, George Esgro, Brian Dickson, and Steven M. Lutz.

### Cornerstone Noteholder Agreement

Carolina Pharmaceuticals, which is the holder of the Carolina Note, has entered into an agreement that provides, among other things, for the conversion or exchange of the outstanding principal amount of the Carolina Note into approximately 18% of the shares of Cornerstone s common stock outstanding immediately prior to the effective time of the merger and for the same voting and lock-up provisions provided for pursuant to the agreements that Cornerstone s other stockholders have entered into.

### Critical Therapeutics Stockholder Agreements

In connection with the execution of the merger agreement, several funds managed by Healthcare Ventures and Advanced Technology Ventures, which, as of May 1, 2008, owned in the aggregate approximately 19% of Critical Therapeutics outstanding common stock, have entered into agreements that provide among other things, that the stockholders grant to Cornerstone and each of its executive officers an irrevocable proxy to vote their shares in favor of the issuance of Critical Therapeutics common stock in the merger and against any proposal made in opposition to, or in competition with, the proposal to issue Critical Therapeutics common stock in connection with the merger.

The Critical Therapeutics stockholders that entered into the voting agreements with Cornerstone are HealthCare Ventures VI, L.P, HealthCare Ventures VII, L.P., Advanced Technology Ventures VII, L.P., Advanced Technology Ventures VII (B), L.P., Advanced Technology Ventures VII (C), L.P., ATV Entrepreneurs VII, L.P., ATV Alliance 2003, L.P., Advanced Technology Ventures VI, L.P. and ATV Entrepreneurs VI, L.P.

Table of Contents

## MATTERS BEING SUBMITTED TO A VOTE OF CRITICAL THERAPEUTICS STOCKHOLDERS

### Proposal 1: Approval of the Issuance of Common Stock in the Merger

***General***

At the special meeting, Critical Therapeutics stockholders will be asked to approve the issuance of Critical Therapeutics common stock pursuant to the merger agreement. Immediately following the effective time of the merger, Cornerstone s stockholders will own approximately 70%, and Critical Therapeutics current stockholders will own approximately 30%, of Critical Therapeutics common stock, assuming the exchange or conversion prior to the merger of the outstanding principal amount of the Carolina Note into shares of Cornerstone s common stock and after giving effect to shares issuable pursuant to Cornerstone s outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics outstanding options and warrants, subject to various assumptions and conditions described in detail in this proxy statement/prospectus. The terms of, reasons for and other aspects of the merger agreement and the issuance of Critical Therapeutics common stock pursuant to the merger agreement are described in detail in the other sections of this proxy statement/prospectus.

The full text of the merger agreement is attached to this proxy statement/prospectus as *Annex A*.

***Required Vote; Recommendation of Board of Directors***

The affirmative vote of the holders of a majority of the shares of Critical Therapeutics common stock present in person or represented by proxy and voting on such matter at the special meeting is required for approval of Proposal 1.

A failure to submit a proxy card or vote at the special meeting, or an abstention, vote withheld or broker non-vote will have no effect on the outcome of Proposal 1.

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 1 TO APPROVE THE ISSUANCE OF CRITICAL THERAPEUTICS COMMON STOCK PURSUANT TO THE MERGER AGREEMENT.**

### Proposal 2: Approval of the Reverse Stock Split

***General***

At the special meeting, Critical Therapeutics stockholders will be asked to approve an amendment to Critical Therapeutics certificate of incorporation to effect a reverse stock split of the issued and outstanding shares of Critical Therapeutics common stock. Upon the effectiveness of the amendment to Critical Therapeutics certificate of incorporation effecting the reverse stock split, the outstanding shares of Critical Therapeutics common stock will be reclassified and combined into a lesser number of shares such that one share of Critical Therapeutics common stock will be issued for a specified number of shares, which shall be greater than one and equal to or less than 50, of outstanding Critical Therapeutics common stock, with the exact number within the range to be determined by Critical Therapeutics board of directors prior to the effective time of such amendment and publicly announced by Critical Therapeutics. By approving the reverse stock split, the stockholders of Critical Therapeutics are approving individual amendments to Critical Therapeutics certificate of incorporation for each number in such range. After the board of directors has selected the number in such range to effect the reverse stock split, Critical Therapeutics will abandon all

amendments to the certificate of incorporation except the amendment with respect to the number selected by the board of directors. If Proposal 2 is approved, the reverse stock split would become effective immediately prior to the effective time the merger. Critical Therapeutics board of directors may effect only one reverse stock split in connection with this Proposal 2. Critical Therapeutics board of directors decision will be based on a number of factors, including market conditions, existing and expected trading prices for Critical Therapeutics common stock and the listing requirements of The NASDAQ Capital Market. Even if the stockholders approve the reverse stock split, Critical Therapeutics reserves the right not to effect the reverse stock split if Critical Therapeutics board

Table of Contents

of directors does not deem the reverse stock split to be in the best interests of Critical Therapeutics and its stockholders. Critical Therapeutics board of directors may determine to effect the reverse stock split, if it is approved by the stockholders, even if the other proposals to be acted upon at the meeting are not approved, including the issuance of shares of Critical Therapeutics common stock in the merger.

The form of the proposed amendment to the Critical Therapeutics certificate of incorporation to effect the reverse stock split, as more fully described below, will effect the reverse stock split but will not change the number of authorized shares, or the par value, of Critical Therapeutics common stock.

***Purpose***

Critical Therapeutics board of directors approved the proposal authorizing the reverse stock split for the following reasons:

- because the initial listing standards of The NASDAQ Capital Market will require Critical Therapeutics to have, among other things, a $4.00 per share minimum bid price upon the closing of the merger, the reverse stock split is necessary in order to consummate the merger;

- the board of directors believes effecting the reverse stock split may be an effective means of avoiding a delisting of Critical Therapeutics common stock from The NASDAQ Capital Market in the future; and

- the board of directors believes a higher stock price may help generate investor interest in Critical Therapeutics and help Critical Therapeutics attract and retain employees.

If the reverse stock split successfully increases the per share price of Critical Therapeutics common stock, Critical Therapeutics board of directors believes that this may increase trading volume in Critical Therapeutics common stock and facilitate future financings by Critical Therapeutics.

***NASDAQ Requirements for Listing on The NASDAQ Capital Market***

Critical Therapeutics common stock is listed on The NASDAQ Capital Market under the symbol CRTX.

According to NASDAQ rules, an issuer must, in a case such as this, apply for initial inclusion following a transaction whereby the issuer combines with a non-NASDAQ entity, resulting in a change of control of the issuer and potentially allowing the non-NASDAQ entity to obtain a NASDAQ listing. These are referred to as NASDAQ s reverse merger rules. Accordingly, the listing standards of The NASDAQ Capital Market will require Critical Therapeutics to have, among other things, a $4.00 per share minimum bid price upon the effective time of the merger. Therefore, the reverse stock split is necessary in order to consummate the merger.

Additionally, Critical Therapeutics board of directors believes that maintaining its listing on The NASDAQ Capital Market may provide a broader market for Critical Therapeutics common stock and facilitate the use of Critical Therapeutics common stock in financing and other transactions. Critical Therapeutics board of directors unanimously approved the reverse stock split partly as a means of maintaining the share price of Critical Therapeutics common stock following the merger above $4.00 per share.

One of the effects of the reverse stock split will be to effectively increase the proportion of authorized shares which are unissued relative to those which are issued. This could result in the combined company being able to issue more shares without further stockholder approval. Critical Therapeutics currently has no plans to issue shares, other than in connection with the merger, and to satisfy obligations under Critical Therapeutics employee stock options and

warrants from time to time as these options and warrants are exercised. The reverse stock split will not affect the number of authorized shares of Critical Therapeutics common stock, which will continue to be 90,000,000.

***Potential Increased Investor Interest***

On September 15, 2008, Critical Therapeutics common stock closed at $0.22 per share. In approving the proposal authorizing the reverse stock split, Critical Therapeutics board of directors considered that Critical Therapeutics common stock may not appeal to brokerage firms that are reluctant to recommend lower priced

Table of Contents

securities to their clients. Investors may also be dissuaded from purchasing lower priced stocks because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Moreover, the analysts at many brokerage firms do not monitor the trading activity or otherwise provide coverage of lower priced stocks. Also, Critical Therapeutics board of directors believes that most investment funds are reluctant to invest in lower priced stocks.

There are risks associated with the reverse stock split, including that the reverse stock split may not result in an increase in the per share price of Critical Therapeutics common stock.

Critical Therapeutics cannot predict whether the reverse stock split will increase the market price for Critical Therapeutics common stock. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

- the market price per share of Critical Therapeutics common stock after the reverse stock split will rise in proportion to the reduction in the number of shares of Critical Therapeutics common stock outstanding before the reverse stock split;
- the reverse stock split will result in a per share price that will attract brokers and investors who do not trade in lower priced stocks;
- the reverse stock split will result in a per share price that will increase Critical Therapeutics ability to attract and retain employees; or
- the market price per share will either exceed or remain in excess of the $1.00 minimum bid price as required by NASDAQ for continued listing, or that Critical Therapeutics will otherwise meet the requirements of NASDAQ for inclusion for trading on The NASDAQ Capital Market.

The market price of Critical Therapeutics common stock will also be based on Critical Therapeutics performance and other factors, some of which are unrelated to the number of shares outstanding. If the reverse stock split is effected and the market price of Critical Therapeutics common stock declines, the percentage decline as an absolute number and as a percentage of Critical Therapeutics overall market capitalization may be greater than would occur in the absence of a reverse stock split. Furthermore, the liquidity of Critical Therapeutics common stock could be adversely affected by the reduced number of shares that would be outstanding after the reverse stock split.

***Principal Effects of the Reverse Stock Split***

If the stockholders approve the proposal to implement the reverse stock split and Critical Therapeutics board of directors implements the reverse stock split, Critical Therapeutics will amend Critical Therapeutics certificate of incorporation to effect the reverse stock split. The text of the form of the proposed amendment to Critical Therapeutics certificate of incorporation is attached to this proxy statement/prospectus as *Annex B*.

The reverse stock split will be effected simultaneously for all outstanding shares of Critical Therapeutics common stock. The reverse stock split will affect all of Critical Therapeutics stockholders uniformly and will not affect any stockholder s percentage ownership interests in Critical Therapeutics, except to the extent that the reverse stock split results in any of Critical Therapeutics stockholders owning a fractional share. Common stock issued pursuant to the reverse stock split will remain fully paid and nonassessable. The reverse stock split will not affect Critical Therapeutics continuing to be subject to the periodic reporting requirements of the Exchange Act.

As of the effective time of the reverse stock split, Critical Therapeutics will adjust and proportionately decrease the number of shares of Critical Therapeutics common stock reserved for issuance upon exercise of, and adjust and proportionately increase the exercise price of, all options and warrants and other rights to acquire Critical Therapeutics common stock. In addition, as of the effective time of the reverse stock split, Critical Therapeutics will adjust and proportionately decrease the total number of shares of Critical Therapeutics common stock that may be the subject of the future grants under Critical Therapeutics stock option plans.

Table of Contents

Assuming reverse stock split ratios of one-for-fifty and one-for-two, which are ratios based on whole numbers of shares at the high end and low end of the range that Critical Therapeutics stockholders are being asked to approve, the following table sets forth the number of shares of Critical Therapeutics common stock that would be (i) issued and outstanding, (ii) reserved for issuance and (iii) authorized for issuance and neither issued nor reserved for issuance, in each case, both immediately prior to the merger (but after the reverse stock split) and immediately following the merger, based on information as of , 2008, the last practicable date before the printing of this proxy statement/prospectus.

| | Reverse Stock Split Ratio of One-for-Fifty | | Reverse Stock Split Ratio of One-for-Two | |
|---|---|---|---|---|
| | **Pre-Merger** | **Post-Merger** | **Pre-Merger** | **Post-Merger** |
| Number of Shares of Common Stock Issued and Outstanding | | | | |
| Number of Shares of Common Stock Reserved for Issuance | | | | |
| Number of Shares of Common Stock Authorized for Issuance and neither Issued nor Reserved for Issuance | | | | |

At the effective time of the merger, each share of Cornerstone s common stock will be converted into and exchanged for the right to receive a number of shares of Critical Therapeutics common stock equal to the product of 2.3333 multiplied by the quotient of 43,479,198, which was the number of outstanding shares of Critical Therapeutics common stock on April 30, 2008, divided by the number of shares of Cornerstone s common stock outstanding immediately prior to the effective time of the merger, assuming the exercise or conversion of all outstanding Cornerstone stock options and warrants, subject to adjustment for the reverse stock split of Critical Therapeutics common stock. As of , 2008, the last practicable date before the printing of this proxy statement/prospectus, shares of Cornerstone s common stock were outstanding, assuming the exchange or conversion prior to the merger of the outstanding principal amount of the Carolina Note into shares of Cornerstone s common stock and the exercise or conversion of all outstanding Cornerstone stock options and warrants. If the merger had been completed as of , 2008, assuming a reverse stock split ratio of one-for-fifty, each share of Cornerstone s common stock would have converted into and been exchanged for the right to receive shares of Critical Therapeutics common stock, which would have resulted in an aggregate issuance of shares of Critical Therapeutics common stock, including shares issuable pursuant to outstanding stock options and warrants. If the merger had been completed as of , 2008, assuming a reverse stock split ratio of one-for-two, each share of Cornerstone s common stock would have converted into and been exchanged for the right to receive shares of Critical Therapeutics common stock, which would have resulted in an aggregate issuance of shares of Critical Therapeutics common stock, including shares issuable pursuant to outstanding stock options and warrants.

***Procedure for Effecting Reverse Stock Split and Exchange of Stock Certificates***

If Critical Therapeutics stockholders approve the proposal to effect the reverse stock split, and if Critical Therapeutics board of directors still believes that a reverse stock split is in the best interests of Critical Therapeutics and its stockholders, Critical Therapeutics board of directors will determine the ratio of the reverse stock split to be implemented. Critical Therapeutics will file the certificate of amendment with the Secretary of State of the State of Delaware immediately prior to the effective time of the merger. Critical Therapeutics board of directors may delay effecting the reverse stock split without resoliciting stockholder approval. Beginning on the effective date of the reverse stock split, each certificate representing pre-split shares will be deemed for all corporate purposes to evidence ownership of post-split shares.

As soon as practicable after the effective date of the reverse stock split, stockholders will be notified that the reverse stock split has been effected. Critical Therapeutics expects that Critical Therapeutics transfer agent will act as exchange agent for purposes of implementing the exchange of stock certificates. Holders of pre-split shares will be asked to surrender to the exchange agent certificates representing pre-split shares in

Table of Contents

exchange for certificates representing post-split shares in accordance with the procedures to be set forth in a letter of transmittal to be sent by Critical Therapeutics. No new certificates will be issued to a stockholder until such stockholder has surrendered such stockholder s outstanding certificate(s) together with the properly completed and executed letter of transmittal to the exchange agent. Any pre-split shares submitted for transfer, whether pursuant to a sale or other disposition, or otherwise, will automatically be exchanged for post-split shares. STOCKHOLDERS SHOULD NOT DESTROY ANY STOCK CERTIFICATE(S) AND SHOULD NOT SUBMIT ANY CERTIFICATE(S) UNLESS AND UNTIL REQUESTED TO DO SO.

***Fractional Shares***

No certificates or scrip representing fractional shares of Critical Therapeutics common stock will be issued in connection with the reverse stock split. Each holder of Critical Therapeutics common stock who would otherwise have been entitled to receive a fraction of a share of Critical Therapeutics common stock (after taking into account all fractional shares of Critical Therapeutics common stock otherwise issuable to such holder) shall be entitled to receive, in lieu thereof, upon surrender of such holder s certificate(s) representing such fractional shares of Critical Therapeutics common stock, cash (without interest) in an amount equal to such fractional part of a share of Critical Therapeutics common stock multiplied by the average last reported sales price of Critical Therapeutics common stock at 4:00 p.m., Eastern time, end of regular trading hours on NASDAQ during the 10 consecutive trading days ending on the last trading day prior to the effective date of the merger.

By authorizing the reverse stock split, stockholders will be approving the combination of any number of shares of common stock between and including a number that is greater than one and less than or equal to 50 into one share. The certificate of amendment filed with the Secretary of State of the State of Delaware will include only that number determined by the board of directors to be in the best interests of Critical Therapeutics and its stockholders. In accordance with these resolutions, the board of directors will not implement any amendment providing for a different split ratio.

Critical Therapeutics stockholders should be aware that, under the escheat laws of the various jurisdictions where stockholders reside, where Critical Therapeutics is domiciled, and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective date of the split may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by Critical Therapeutics or the exchange agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, stockholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

***Accounting Matters***

The reverse stock split will not affect the common stock capital account on Critical Therapeutics balance sheet. However, because the par value of Critical Therapeutics common stock will remain unchanged on the effective date of the split, the components that make up the common stock capital account will change by offsetting amounts. Depending on the size of the reverse stock split the board of directors decides to implement, the stated capital component will be reduced and the additional paid-in capital component will be increased with the amount by which the stated capital is reduced. The per share net income or loss and net book value of Critical Therapeutics will be increased because there will be fewer shares of Critical Therapeutics common stock outstanding. Prior periods per share amounts will be restated to reflect the reverse stock split.

***Potential Anti-Takeover Effect***

Although the increased proportion of unissued authorized shares to issued shares could, under certain circumstances, have an anti-takeover effect, for example, by permitting issuances that would dilute the stock ownership of a person seeking to effect a change in the composition of Critical Therapeutics board of directors or contemplating a tender offer or other transaction for the combination of Critical Therapeutics with another company, the reverse stock split proposal is not being proposed in response to any effort of which

Table of Contents

Critical Therapeutics is aware to accumulate shares of Critical Therapeutics common stock or obtain control of Critical Therapeutics, other than in connection with the merger with Cornerstone, nor is it part of a plan by management to recommend a series of similar amendments to Critical Therapeutics board of directors and stockholders. Other than the proposals being submitted to Critical Therapeutics stockholders for their consideration at the special meeting, Critical Therapeutics board of directors does not currently contemplate recommending the adoption of any other actions that could be construed to affect the ability of third parties to take over or change control of Critical Therapeutics.

***No Appraisal Rights***

Under the Delaware General Corporation Law, Critical Therapeutics stockholders are not entitled to appraisal rights with respect to the reverse stock split, and Critical Therapeutics will not independently provide stockholders with any such right.

***Material U.S. Federal Income Tax Consequences of the Reverse Stock Split***

The following discussion summarizes the material U.S. federal income tax consequences of the reverse stock split that are expected to apply generally to Critical Therapeutics stockholders as a result of the reverse stock split. This summary is based upon current provisions of the Code, existing Treasury Regulations and current administrative rulings and court decisions, all of which are subject to change and to differing interpretations, possibly with retroactive effect.

This summary only applies to a Critical Therapeutics stockholder that is a U.S. person, defined to include:

- a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States, or any political subdivision thereof (including the District of Columbia);
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source;
- a trust if either:
  - a court within the United States is able to exercise primary supervision over the administration of such trust and one or more U.S. persons have the authority to control all substantial decisions of such trust; or
  - the trust has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes; and
- any other person or entity that is treated for U.S. federal income tax purposes as if it were one of the foregoing.

Any Critical Therapeutics stockholder other than a U.S. person as so defined is, for purposes of this discussion, a non-U.S. person. If a partnership holds Critical Therapeutics common stock, the tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. If you are a partner of a partnership holding Critical Therapeutics common stock, you should consult your tax advisor.

This summary assumes that Critical Therapeutics stockholders hold their shares of Critical Therapeutics common stock as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment). No attempt has been made to comment on all U.S. federal income tax consequences of the reverse stock split that may be relevant to particular holders, including holders:

who are subject to special treatment under U.S. federal income tax rules such as dealers in securities, financial institutions, non-U.S. persons, mutual funds, regulated investment companies, real estate investment trusts, insurance companies, or tax-exempt entities;

who acquired their shares in connection with stock option or stock purchase plans or in other compensatory transactions;

who hold their shares as qualified small business stock within the meaning of Section 1202 of the Code;

Table of Contents

who hold their shares as part of an integrated investment such as a hedge or as part of a hedging, straddle or other risk reduction strategy; or

who do not hold their shares as capital assets.

In addition, the following discussion does not address the tax consequences of the reverse stock split under state, local and foreign tax laws or under the alternative minimum tax provisions of the Code. Furthermore, the following discussion does not address any of the tax consequences of transactions effectuated before, after or at the same time as the reverse stock split, whether or not they are in connection with the reverse stock split, including, without limitation, transactions in which shares of Critical Therapeutics common stock are acquired or disposed of.

**Accordingly, holders of Critical Therapeutics common stock are advised and expected to consult their own tax advisers regarding the U.S. federal income tax consequences of the reverse stock split to them in light of their personal circumstances and the consequences of the reverse stock split under state, local and foreign tax laws.**

Other than the cash payments for fractional shares discussed below, no gain or loss should be recognized by a Critical Therapeutics stockholder upon such stockholder s exchange of pre-split shares for post-split shares pursuant to the reverse stock split. The aggregate tax basis of the post-split shares received in the reverse stock split, including any fraction of a post-split share deemed to have been received, will be the same as the Critical Therapeutics stockholder s aggregate tax basis in the pre-split shares that are exchanged.

In general, Critical Therapeutics stockholders who receive cash upon the deemed sale of their fractional share interests in the post-split shares as a result of the reverse stock split will recognize gain or loss equal to the difference between their basis in the fractional share and the amount of cash received. The Critical Therapeutics stockholder s holding period for the post-split shares will include the period during which the stockholder held the pre-split shares surrendered in the reverse stock split.

Such gain or loss will be a capital gain or loss, and generally will constitute a long-term capital gain or loss if the stockholder s holding period in the stock exchanged is more than one year as of the closing date of the reverse stock split. Net capital gain (i.e., the excess of net long-term capital gain over net short-term capital loss) will be subject to tax at reduced rates for non-corporate stockholders who receive cash. The deductibility of capital losses is subject to various limitations for corporate and non-corporate holders.

For purposes of the above discussion of bases and holding periods, stockholders who acquired different blocks of stock at different times for different prices must calculate their gains and losses and holding periods separately for each identifiable block of such stock exchanged in the reverse stock split.

Certain noncorporate Critical Therapeutics stockholders may be subject to backup withholding, at a rate of 28% for 2008, on cash received pursuant to the reverse stock split. Backup withholding will not apply, however, to a Critical Therapeutics stockholder who (1) furnishes a correct taxpayer identification number and certifies that the Critical Therapeutics stockholder is not subject to backup withholding on IRS Form W-9 or a substantially similar form, (2) provides a certification of foreign status on an appropriate Form W-8 or successor form or (3) is otherwise exempt from backup withholding. If a Critical Therapeutics stockholder does not provide a correct taxpayer identification number on IRS Form W-9 or a substantially similar form, the Critical Therapeutics stockholder may be subject to penalties imposed by the IRS. Amounts withheld, if any, are generally not an additional tax and may be refunded or credited against the Critical Therapeutics stockholder s federal income tax liability, provided that the Critical Therapeutics stockholder furnishes the required information to the IRS.

**THE PRECEDING DISCUSSION IS INTENDED ONLY AS A SUMMARY OF THE MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE REVERSE STOCK SPLIT AND DOES NOT PURPORT TO BE A COMPLETE ANALYSIS OR DISCUSSION OF ALL OF THE REVERSE STOCK SPLIT S POTENTIAL TAX EFFECTS. CRITICAL THERAPEUTICS STOCKHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE SPECIFIC TAX CONSEQUENCES TO THEM OF THE REVERSE STOCK SPLIT, INCLUDING TAX RETURN**

Table of Contents

**REPORTING REQUIREMENTS, AND THE APPLICABILITY AND EFFECT OF FEDERAL, STATE, LOCAL AND OTHER APPLICABLE TAX LAWS.**

***Vote Required; Recommendation of Board of Directors***

The affirmative vote of holders of a majority of the outstanding shares of Critical Therapeutics common stock as of the record date for the special meeting is required for approval of Proposal 2.

A failure to submit a proxy card or vote at the special meeting, or an abstention, vote withheld or broker non-vote for Proposal 2 will have the same effect as a vote against the approval of Proposal 2.

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 2 TO AMEND CRITICAL THERAPEUTICS CERTIFICATE OF INCORPORATION TO EFFECT THE REVERSE STOCK SPLIT.**

**Proposal 3: Approval of Name Change**

***General***

At the special meeting, holders of Critical Therapeutics common stock will be asked to approve the amendment of Critical Therapeutics certificate of incorporation to change the name of the corporation from Critical Therapeutics to Cornerstone Therapeutics Inc. immediately following the effective time of the merger.

The primary reason for the corporate name change is that management believes this will allow for brand recognition of Cornerstone s products and product candidate pipeline following the consummation of the merger. Critical Therapeutics management believes that the current name will no longer accurately reflect the business of the combined company and the mission of the combined company subsequent to the consummation of the merger. The text of the form of the proposed amendment to the Critical Therapeutics certificate of incorporation is attached to this proxy statement/prospectus as *Annex C*.

Insofar as the proposed new corporate name will only reflect Cornerstone s business following the merger, the proposed name change and the amendment of Critical Therapeutics certificate of incorporation, even if approved by the stockholders at the special meeting, will only be filed with the office of the Secretary of State of the State of Delaware and, therefore, become effective if the merger is consummated.

***Vote Required; Recommendation of Board of Directors***

The affirmative vote of holders of a majority of the outstanding shares of Critical Therapeutics common stock as of the record date for the special meeting is required for approval of Proposal 3.

A failure to submit a proxy card or vote at the special meeting, or an abstention, vote withheld or broker non-vote for Proposal 3 will have the same effect as a vote against the approval of Proposal 3.

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 3 TO APPROVE THE NAME CHANGE.**

**Proposal 4: Approval of Possible Adjournment of the Special Meeting**

***General***

If Critical Therapeutics fails to receive a sufficient number of votes to approve Proposals 1, 2 or 3, Critical Therapeutics may propose to adjourn the special meeting, if a quorum is present, for a period of not more than 30 days for the purpose of soliciting additional proxies to approve Proposals 1, 2 or 3. Critical Therapeutics currently does not intend to propose adjournment at the special meeting if there are sufficient votes to approve Proposals 1, 2 and 3.

Table of Contents

***Vote Required; Recommendation of Board of Directors***

The affirmative vote of the holders of a majority of the Critical Therapeutics common stock having voting power present in person or represented by proxy at the special meeting is required to approve the adjournment of the special meeting for the purpose of soliciting additional proxies to approve Proposals 1, 2 or 3.

A failure to submit a proxy card or vote at the special meeting, or an abstention, vote withheld or broker non-vote will have no effect on the outcome of Proposal 4.

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 4 TO ADJOURN THE SPECIAL MEETING, IF NECESSARY, IF A QUORUM IS PRESENT, TO SOLICIT ADDITIONAL PROXIES IF THERE ARE NOT SUFFICIENT VOTES IN FAVOR OF PROPOSALS 1, 2 OR 3.**

Table of Contents

## CRITICAL THERAPEUTICS BUSINESS

### Overview

Critical Therapeutics is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory diseases, as well as other inflammatory diseases linked to the body s inflammatory response. Critical Therapeutics two marketed products are ZYFLO CR, which the FDA approved in May 2007, and ZYFLO, which the FDA approved in 1996, for the prevention and chronic treatment of asthma in adults and children 12 years of age or older. Critical Therapeutics licensed from Abbott exclusive worldwide rights to ZYFLO CR, ZYFLO and other formulations of zileuton for multiple diseases and conditions. Critical Therapeutics began selling ZYFLO CR in the United States in September 2007 and began selling ZYFLO in the United States in October 2005. In addition, Critical Therapeutics is developing zileuton injection.

In September 2007, Critical Therapeutics sales force and the sales force of its co-promotion collaborator, DEY, began actively promoting ZYFLO CR and ceased actively promoting ZYFLO. Critical Therapeutics ceased manufacturing and supplying ZYFLO in February 2008, but resumed the supply of ZYFLO in September 2008 to help manage any potential impact to patients of supply chain issues for ZYFLO CR. In April 2008, Critical Therapeutics announced the results of a Phase I clinical trial designed to examine the pharmacokinetic and pharmacodynamic profile of the R(+) isomer of zileuton to determine if there are potential dosing improvements for patients from this isomer. In addition, Critical Therapeutics is developing zileuton injection initially for use in emergency room or urgent care centers for patients who suffer acute exacerbations of asthma. In June 2008, Critical Therapeutics announced results from its Phase II clinical trial with zileuton injection in patients with chronic, stable asthma. Critical Therapeutics intends to initiate a process to seek to enter into a collaboration agreement for the future clinical development and commercialization of zileuton injection.

On March 13, 2007, Critical Therapeutics entered into an agreement with DEY, under which Critical Therapeutics and DEY agreed to jointly promote ZYFLO and ZYFLO CR. On June 25, 2007, Critical Therapeutics entered into a definitive agreement with DEY to jointly promote DEY s product PERFOROMIST for the treatment of COPD. In October 2007, Critical Therapeutics announced that it had commercially launched PERFOROMIST with DEY. On July 2, 2008, Critical Therapeutics provided notice to DEY that Critical Therapeutics had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

Critical Therapeutics has been conducting preclinical work in its alpha-7 program. Critical Therapeutics believes the successful development of a small molecule product candidate targeting the alpha-7 nicotinic acetylcholine receptor, or alpha-7 receptor, could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma and rheumatoid arthritis. Based on preclinical studies, Critical Therapeutics selected lead and backup molecules for evaluation in good laboratory practices, or GLP, toxicology studies. Provided the data are supportive and sufficient resources are available, Critical Therapeutics believes that an investigational new drug application, or IND, could be filed in 2009. In addition, Critical Therapeutics plans to seek collaborations with other pharmaceutical companies for its alpha-7 program to develop and commercialize possible product candidates in multiple development opportunities that may exist within this program prior to the initiation of human clinical trials. Critical Therapeutics licensed to SetPoint patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. This license agreement specifically excludes from the licensed field pharmacological modulation of the alpha-7 receptor.

Critical Therapeutics has a collaboration agreement with MedImmune for the development of monoclonal antibodies directed toward a cytokine called HMGB1, which Critical Therapeutics believes may be an important target for the

development of products to treat diseases mediated by the body s inflammatory response. In addition, Critical Therapeutics has a collaboration agreement with Beckman Coulter for the development of a diagnostic directed toward measuring HMGB1 in the bloodstream.

Table of Contents

Critical Therapeutics was incorporated in Delaware on July 14, 2000 as Medicept, Inc. and changed its name to Critical Therapeutics in March 2001. Critical Therapeutics completed an initial public offering of its common stock in June 2004, and its common stock is currently traded on The NASDAQ Capital Market.

**Proposed Merger with Cornerstone**

Until the closing of the proposed merger with Cornerstone, Critical Therapeutics expects to continue its commercial and development activities in accordance with its existing business strategy with an increased focus on managing its cash position. The description of Critical Therapeutics business set forth in this proxy statement/prospectus does not reflect any changes to Critical Therapeutics business that may occur if it consummates the proposed merger with Cornerstone. For instance, the combined company s clinical and preclinical pipeline will include a number of product candidates. The combined company is expected to implement a strategic review of its product development pipeline. Following the strategic review, the combined company may seek to maximize the value of any non-core programs through out-licensing, divestiture or spin-off transactions.

**Critical Therapeutics Product Pipeline**

The following table sets forth the current status of Critical Therapeutics products and product candidates in development and Critical Therapeutics research and development programs:

* Being developed by MedImmune under an exclusive license and collaboration agreement. Diagnostic assays directed towards HMGB1 are being developed with Beckman Coulter under a license agreement.

**Zileuton**

In 2003, Critical Therapeutics acquired from Abbott exclusive worldwide rights to develop and market ZYFLO CR and other formulations of zileuton for multiple diseases and conditions. In 2004, Critical Therapeutics acquired from Abbott exclusive worldwide rights to develop and market ZYFLO. The FDA approved Critical Therapeutics sNDA for ZYFLO on September 28, 2005, and Critical Therapeutics began selling ZYFLO in the United States in October 2005. Critical Therapeutics ceased manufacturing and supplying ZYFLO in February 2008, but resumed supply of ZYFLO in September 2008 to help manage the potential impact to patients of supply chain issues for ZYFLO CR. The FDA approved the NDA for ZYFLO CR on May 30, 2007, and Critical Therapeutics subsequently launched ZYFLO CR in the United States on September 27, 2007.

Zileuton blocks the activity of the 5-lipoxygenase enzyme, which is the main enzyme responsible for formation of a family of lipids known as leukotrienes. There are many different leukotrienes, and the mechanism of action of ZYFLO CR and ZYFLO blocks production of the entire leukotriene family.

Table of Contents

Leukotrienes are in part responsible for the inflammatory response associated with asthma and are known to cause many of the biological effects that contribute to inflammation, mucus production and closing of the lung airways of asthmatic patients. Leukotrienes are also implicated in the disturbance of normal lung airway function in other diseases, including COPD. ZYFLO CR and ZYFLO are the only FDA-approved leukotreine synthesis inhibitors for the prevention and chronic treatment of asthma in adults and children 12 years of age and older.

***Therapeutic Opportunity***

Asthma is a chronic respiratory disease characterized by the narrowing of the lung airways, making breathing difficult. An asthma attack leaves the victim short of breath as the airways become constricted and inflamed. The National Center for Health Statistics estimates that in 2005 approximately 22.2 million people in the United States had asthma and approximately 12.2 million people in the United States had asthma attacks. Severe asthma attacks can be life threatening. The National Center for Health Statistics estimates that in 2005 approximately 1.8 million hospital emergency room visits in the United States involved asthma attacks and approximately 488,594 hospital discharges were attributable to asthma.

There is no one ideal treatment for asthma, and there is no cure. Currently, patients are treated with a combination of products that are designed primarily to manage their disease symptoms by opening the airways in the lungs and reducing inflammation. Typical treatments include bronchodilatory drugs, such as Serevent®, LTRAs, such as Singulair®, inhaled corticosteroids, such as Flovent® and combination products such as Advair®, which is a combination of an inhaled corticosteroid and a long-acting bronchodilator. Critical Therapeutics believes many prescribing physicians are dissatisfied with the treatment options available for uncontrolled asthmatic patients due to the inability of these treatments to control symptoms reliably. A recent study, titled Real-world Evaluation of Asthma Control and Treatment (REACT): Findings from a National Web-based Survey and published in The Journal of Allergy & Clinical Immunology, stated that nearly 55% of all moderate to severe asthmatics remain uncontrolled despite being treated with asthma medications.

Critical Therapeutics believes that many patients with asthma may benefit from therapy with ZYFLO CR or ZYFLO. ZYFLO CR and ZYFLO actively inhibit the main enzyme responsible for the production of a broad spectrum of lipids responsible for the symptoms associated with asthma, including all leukotrienes. Critical Therapeutics is marketing ZYFLO CR and ZYFLO as treatments for asthma patients who do not gain adequate symptomatic control from other currently available medications.

***Zileuton Product Development***

*ZYFLO: The Immediate-Release Formulation of Zileuton*

ZYFLO and ZYFLO CR are the only leukotreine synthesis inhibitor drugs to be approved for marketing by the FDA. In 1996, ZYFLO was approved by the FDA as an immediate-release, four-times-a-day tablet for the prevention and chronic treatment of asthma in adults and children 12 years of age and older. ZYFLO was first launched in the United States in 1997. The FDA approved Critical Therapeutics sNDA for ZYFLO on September 28, 2005, and Critical Therapeutics began selling ZYFLO in the United States in October 2005. Critical Therapeutics recognized revenue from sales of ZYFLO of $748,000 for the six months ended June 30, 2008, $8.7 million in 2007, $6.6 million in 2006 and $387,000 in 2005. Critical Therapeutics recognized revenue from sales of ZYFLO CR of $6.5 million for the six months ended June 30, 2008 and $2.3 million in 2007. The full clinical development program for ZYFLO consisted of 21 safety and efficacy trials in an aggregate of approximately 3,000 patients with asthma. FDA approval was based on pivotal three-month and six-month safety and efficacy clinical trials in 774 asthma patients. The pivotal trials compared patients taking ZYFLO and their rescue bronchodilators as needed to patients taking placebo and rescue bronchodilators as needed. The results of the group taking ZYFLO and their rescue bronchodilators showed:

rapid and sustained improvement for patients over a six-month period in objective and subjective measures of asthma control;

Table of Contents

reduction of exacerbations and need for either bronchodilatory or steroid rescue medications; and

acute bronchodilatory effect within two hours after the first dose.

Critical Therapeutics post hoc analysis of the data suggested there was a greater airway response benefit in asthma patients with less than 50% of expected airway function, and a six-fold decrease in the need for steroid rescue medication in these patients compared to placebo.

In these placebo-controlled clinical trials, 1.9% of patients taking ZYFLO experienced an increase in the liver enzyme ALT greater than three times the level normally seen in the bloodstream compared to 0.2% of patients receiving placebo. These enzyme levels resolved or returned towards normal in approximately 50% of the patients who continued therapy and all of the patients who discontinued the therapy.

In addition, prior to FDA approval, a long-term, safety surveillance trial was conducted in 2,947 patients. In this safety trial, 4.6% of patients taking ZYFLO experienced ALT levels greater than three times the level normally seen in the bloodstream compared to 1.1% of patients receiving placebo. In 61.0% of the patients with ALT levels greater than three times the level normally seen in the bloodstream, the elevation was seen in the first two months of dosing. After two months of treatment, the rate of ALT levels greater than three times the level normally seen in the bloodstream stabilized at an average of 0.3% per month for patients taking a combination of ZYFLO and their usual asthma medications compared to 0.11% per month for patients taking a combination of placebo and their usual asthma medications. This trial also demonstrated that ALT levels returned to below two times the level normally seen in the bloodstream in both the patients who continued and those who discontinued the therapy. The overall rate of patients with ALT levels greater than three times the level normally seen in the bloodstream was 3.2% in the approximately 5,000 patients who received ZYFLO in placebo-controlled and open-label trials combined. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin.

After reviewing the data from these trials, the FDA approved ZYFLO in 1996 on the basis of the data submitted, and Critical Therapeutics is not aware of any reports of ZYFLO being directly associated with serious irreversible liver damage in patients treated with ZYFLO since its approval.

*ZYFLO CR: The Extended-Release Formulation of Zileuton*

Critical Therapeutics commercially launched ZYFLO CR in September 2007, following its approval by the FDA in May 2007. Critical Therapeutics believes ZYFLO CR offers a more convenient regimen for patients because of its twice-daily, two tablets per dose dosing regimen, as compared to ZYFLO s four-times daily dosing regimen, which Critical Therapeutics believes may increase patient drug compliance. Abbott completed Phase III clinical trials for this formulation in asthma, but did not submit an NDA. Critical Therapeutics submitted the NDA for ZYFLO CR to the FDA based on safety and efficacy data generated from two completed Phase III clinical trials, a three-month efficacy trial and a six-month safety trial, each of which was completed by Abbott. The study reports prepared by Abbott for these clinical trials showed:

In a three-month pivotal efficacy trial, in which 397 patients received either ZYFLO CR or placebo, patients taking ZYFLO CR demonstrated statistically significant improvements over placebo in objective measures of asthma control, such as mean forced expiratory volume in one second, or $FEV_1$. In the trial, patients taking ZYFLO CR showed a reduced need for bronchodilatory drugs as a rescue medication to alleviate uncontrolled symptoms. In this trial, 2.5% of the patients taking ZYFLO CR experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream, compared to 0.5% of the patients taking placebo.

In a six-month safety trial, in which 706 patients received either a combination of ZYFLO CR and their usual asthma medications or a combination of placebo and their usual asthma medications, 1.78% of the patients taking ZYFLO CR and their usual asthma medications experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream, compared to 0.65% of the patients taking placebo and their usual asthma medications.

Table of Contents

To be able to rely on the results of Abbott s pivotal clinical trials, Critical Therapeutics conducted two comparative bioavailability studies intended to show that the pharmacokinetic profile of ZYFLO CR tablets that Critical Therapeutics manufactured was similar to the pharmacokinetic profile of the ZYFLO CR tablets previously manufactured by Abbott and used in Abbott s clinical trials. Critical Therapeutics conducted both a single-dose and a multiple-dose pharmacokinetic study. The studies assessed the pharmacokinetics of ZYFLO CR in volunteers under both fed and fasting conditions.

Critical Therapeutics entered into an agreement in March 2007 with DEY under which Critical Therapeutics and DEY jointly co-promote ZYFLO CR and ZYFLO.

*Zileuton Injection*

Critical Therapeutics is developing zileuton injection for use as an adjunctive treatment for patients with acute exacerbations of asthma. Critical Therapeutics believes acute exacerbations of asthma are a significant unmet medical need that occur in asthma patients who are poorly controlled on their existing medications. According to the American Lung Association, in 2005, approximately 1.8 million hospital emergency room visits in the United States involved asthma attacks and approximately 488,594 hospital discharges were attributable to asthma. Critical Therapeutics is developing zileuton injection as a new treatment option for acute asthma patients in the emergency department that can be added to existing therapies in order to improve pulmonary function by controlling both bronchospasm and pulmonary inflammation through zileuton s mechanism of action, leukotreine synthesis inhibition.

Currently, most patients suffering severe asthma attacks are treated with bronchodilators inhaled via a nebulizer, typically for 20 minutes or more. Nebulizers attempt to restore airway function by delivering the bronchodilatory drug directly into the lungs. However, the patient s ability to get the drug into his or her lungs may be impaired by his or her inability to breathe efficiently due to the severe asthma attack. Clinical data demonstrate that zileuton exhibits its maximum effect on lung function when the blood drug concentration reaches its peak level and that the effect can be achieved after a single oral dose of zileuton. Critical Therapeutics believes that an injectable formulation of zileuton that would deliver zileuton directly to the bloodstream would have a rapid onset of action, reaching peak blood concentration within minutes of the injection. Critical Therapeutics believes that this rapid delivery of the drug to the patient s bloodstream may lead to more rapid improvements in symptoms, and potentially reduce the number of hospital admissions of patients arriving in the emergency room suffering from a severe asthma attack.

In August 2006, Critical Therapeutics announced results from a Phase I/II clinical trial with zileuton injection in chronic stable asthmatics. The trial included measurements to detect evidence of improvement in lung function. The multi-center, double-blind, placebo-controlled trial enrolled 60 patients with a mean $FEV_1$ of 63 percent of predicted normal at baseline and a mean age of 40 years. Patients enrolled in the trial were randomized into four escalating dose groups, 75 mg, 150 mg, 300 mg and 600 mg, and received one infusion of either zileuton injection or placebo. Each of the four dose groups enrolled 15 patients, of whom 12 received zileuton injection and three received placebo. All 60 patients who were randomized completed the trial.

Patients in each of the four zileuton injection cohorts showed a greater mean percentage improvement in $FEV_1$ than patients in the placebo group when measured at 10, 30 and 60-minute intervals after dosing. The 300 mg dose was predicted to approximate the blood level exposure of the currently approved immediate-release oral dose of ZYFLO. In this trial, the 300 mg dose group showed a mean improvement in $FEV_1$ from baseline of 13.7 percent at 60 minutes after dosing. In addition, zileuton injection was well tolerated at all doses tested with no serious adverse events reported in the trial.

In June 2008, Critical Therapeutics announced top-line results from a Phase II clinical trial with zileuton injection in chronic stable asthmatics. The trial was designed to explore the pulmonary function profile, safety, tolerability and pharmacokinetic profile of zileuton injection. The multi-center, double-blind, placebo-controlled, three-period cross-over trial enrolled 36 patients with stable, moderate-to-severe asthma and a $FEV_1$ of 40 percent to 80 percent of predicted normal. In this trial, patients received a single dose of 150 mg or 300 mg of zileuton injection or placebo, administered via a peripheral intravenous, or IV, catheter at a

standard continuous rate. The trial measured pulmonary function using $FEV_1$ at multiple time points over the first hour then hourly until six hours after dosing.

Zileuton injection, at both dose levels, was well tolerated in all 36 patients and there were no serious adverse events reported. Patients receiving each of the two zileuton injection dose levels showed a numerically greater mean percentage improvement in $FEV_1$ from baseline than patients receiving placebo; however, the results were not statistically significant compared to placebo.

The mean percentage improvement in $FEV_1$ from baseline was evident from the first measurement time point of 10 minutes after dosing and was maintained for at least four hours. Critical Therapeutics believes that the variability in baseline levels of $FEV_1$ seen within individual patients across the three dosing regimens often resulted in higher than expected baseline lung function, which did not provide an opportunity to achieve a meaningful improvement in lung function that could approach statistical significance. Exploratory analyses conducted on the trial data indicate that patients with a baseline $FEV_1$ less than or equal to 65% of predicted normal responded better to zileuton treatment.

Critical Therapeutics believes that these exploratory analyses and the tolerability of zileuton injection may support a clinical trial in an acute population as a potential next step in the development process. Critical Therapeutics intends to initiate a process to seek to enter into a collaboration agreement for the future clinical development and commercialization of zileuton injection.

***Commercialization Strategy***

As of September 15, 2008, Critical Therapeutics has a respiratory sales force of approximately 26 representatives who are focused on promoting ZYFLO CR and PERFOROMIST to prescribing physicians in major markets across the United States. Critical Therapeutics is seeking to increase utilization of ZYFLO CR and ZYFLO by prescribing physicians.

In March 2007, Critical Therapeutics entered into a co-promotion agreement with DEY under which Critical Therapeutics and DEY agreed to jointly promote ZYFLO and, after approval by the FDA, ZYFLO CR. DEY has a respiratory sales force consisting of approximately 200 clinical sales representatives as of September 15, 2008. Under the co-promote agreement, DEY is required to provide a specified number of details per month for ZYFLO CR, in the second position, to office-based physicians and other health care professionals, including a minimum number of details delivered to respiratory specialists, such as allergists and pulmonologists. Under the co-promotion agreement, Critical Therapeutics has agreed to provide a specified number of details per month for ZYFLO CR in the first position. From 2008 through 2010, Critical Therapeutics and DEY each have agreed to contribute 50 percent of out-of-pocket promotion expenses for ZYFLO CR that are accrued or paid to third-parties and approved by a joint commercial committee. Critical Therapeutics was responsible for third-party promotion costs during 2007.

Critical Therapeutics believes that there is a market opportunity for the use of ZYFLO CR as an add-on therapy option for patients whose asthma symptoms are not adequately controlled with the use of inhaled corticosteroids and other conventional therapies, including LTRAs and LABAs. Critical Therapeutics belief is based on information that it has gathered through extensive direct interactions and market research with respiratory specialists, including allergists and pulmonologists and primary care physicians, such as:

- more than two years of in-depth interaction between Critical Therapeutics medical science liaisons with key opinion leaders in the treatment of respiratory diseases, including asthma;

- more than two years of interaction between Critical Therapeutics sales force and respiratory specialists who treat asthma; and

qualitative and quantitative market research that it has conducted since 2004.

Critical Therapeutics is positioning ZYFLO CR as an alternative treatment for asthma patients who do not gain adequate control of their symptoms with other currently available medications, including inhaled corticosteroids, long-acting beta agonists and LTRAs. Critical Therapeutics is promoting ZYFLO CR to respiratory specialists, managed care decision makers and some primary care physicians who treat large volumes of asthma patients. As part of its marketing strategy, Critical Therapeutics attempts to educate key opinion leaders and physicians on the scientific data that differentiates the mechanism of action of ZYFLO CR

Table of Contents

from other asthma treatments and emphasize clinical data that show safety and efficacy for ZYFLO CR in asthma.

Critical Therapeutics believes that in most managed care formularies ZYFLO CR and ZYFLO have been placed in formulary positions that require a higher co-payment for patients prescribed the product. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for ZYFLO CR.

In June 2007, the National Heart Lung, and Blood Institute, or NHLBI, released an updated version of the Guidelines for the Diagnosis and Management of Asthma. In these guidelines, zileuton is specifically mentioned in steps three and four in the treatment spectrum as an alternative option in the treatment of asthma. This is the first time zileuton has been mentioned in these guidelines, and Critical Therapeutics believes this may provide additional scientific credibility to ZYFLO CR in the marketplace. In addition to the changes in the recommended treatment protocol for asthma, the updated guidelines continue to support the transition to discussing asthmatic patients in terms of their level of control rather than their severity level.

Since the commercial launch of ZYFLO CR in September 2007, Critical Therapeutics has experienced growth in overall prescription volume and the number of physicians prescribing ZYFLO CR, and it believes this growth is due to the greater market acceptance of the twice-daily dosing of ZYFLO CR compared to the four-times daily immediate-release formulation of ZYFLO.

Critical Therapeutics is exploring the therapeutic benefits of zileuton in treating a range of diseases and conditions, including acute asthma exacerbations and COPD. Critical Therapeutics is aware, for instance, of clinical data available in publications of clinical trials and individual patient case studies that indicate zileuton has shown efficacy in the treatment of nasal polyps. The NIH sponsored and is funding a clinical trial to evaluate whether using ZYFLO to treat patients admitted to the hospital with acute exacerbations of COPD will shorten their hospital stay. The clinical trial began in September 2007 and is being conducted by the COPD Clinical Research Network. In each case, if Critical Therapeutics develops zileuton for one of these diseases or conditions, it will need to commence clinical development programs to generate sufficient information to obtain regulatory approval.

***R(+) Isomer of Zileuton***

In April 2008, Critical Therapeutics announced the results of a Phase I clinical trial to assess the safety and tolerability of an oral single dose of the R(+) isomer of zileuton. R(+) zileuton combined in equal proportion with its mirror image isomer, S(−) zileuton, comprise racemic zileuton. The trial was designed to examine the safety, tolerability, pharmacokinetic and pharmacodynamic profile of the R(+) isomer of zileuton in healthy subjects. The randomized, open-label, single dose, single center, two-period crossover trial enrolled 12 participants. Each trial participant received both 100 mg and 300 mg doses of the R(+) isomer of zileuton in a randomized, crossover design. Both dose levels of R(+) zileuton were well tolerated with no serious adverse events or clinical safety concerns reported in this trial. Pharmacokinetic data obtained for R(+) zileuton, dosed alone to humans for the first time, exhibited dose proportionality and matched historical data obtained for R(+) zileuton following equivalent doses of racemic zileuton in earlier clinical trials. The pharmacokinetic profile of R(+) zileuton obtained in this trial confirmed that it constitutes approximately two-thirds of the plasma exposure observed with racemic zileuton and is the more persistent isomer of zileuton.

Critical Therapeutics was not able to gain any pharmacodynamic data from this trial. In previous in vitro preclinical studies conducted by Critical Therapeutics with human whole blood, R(+) zileuton exhibited higher potency for leukotriene synthesis inhibition than S(−) zileuton indicating that this enantiomer exhibits a more prolonged plasma pharmacokinetic exposure profile. Critical Therapeutics believes that these features may offer the opportunity for the development of a product candidate with a reduced tablet size or less frequent dose administration.

Table of Contents

**Critical Care: The Inflammatory Response**

Critical Therapeutics is developing product candidates directed towards reducing the potent inflammatory response that it believes is associated with the pathology, morbidity and, in some cases, mortality in many acute and chronic diseases. Critical Therapeutics early-stage product development programs center on controlling the production of potent inflammatory mediators that play a key role in regulating the body s immune system. The cascading release of the inflammatory mediators that occurs in many disease settings leads, in large part, to the uncontrolled, pathologic inflammation that can occur in trauma, infection and autoimmune and allergic diseases. Critical Therapeutics believes that this cascade plays an important role in the severe inflammatory response seen in:

- acute diseases and conditions that lead to admission to the intensive care unit, or ICU, such as sepsis and septic shock; and

- acute exacerbations of chronic diseases that frequently lead to hospitalization, such as asthma, lupus and rheumatoid arthritis.

In the setting of severe infection, trauma, severe bleeding or a lack of oxygen to the major organs of the body, the overproduction of inflammatory mediators, including cytokines, can lead to organ failure, tissue destruction and, eventually, death. When cytokine levels become elevated, an excessive inflammatory response occurs that may potentially result in damage to vital internal organs and, in the most severe cases, multiple organ failure and death. Many previous therapies directed at cytokines, such as tumor necrosis factor alpha, or TNF alpha, in acute diseases have failed in clinical development.

The individual programs within Critical Therapeutics portfolio, while targeted toward the inflammatory response, exert their effects through different mechanisms of action. These programs include:

- an alpha-7 program directed towards a receptor that Critical Therapeutics believes regulates the release of the cytokines that play a fundamental role in the inflammatory response, including TNF alpha, in response to an inflammatory stimulus; and

- an HMGB1 program directed towards the pro-inflammatory protein HMGB1.

These programs are described in more detail below.

***Alpha-7 Program***

Stimulation of the vagus nerve, a nerve that links the brain with the major organs of the body, causes the release of a chemical neurotransmitter called acetylcholine. Acetylcholine has been shown to inhibit the release of cytokines that play a fundamental role in the inflammatory response, including TNF alpha. Research indicates that acetylcholine exerts anti-inflammatory activity by stimulating alpha-7 receptor on cells involved in the inflammatory process.

Historically, a number of companies have focused on the alpha-7 receptor target for the treatment of central nervous system diseases. Critical Therapeutics believes the discovery of the role of this receptor in inflammation has led to a new opportunity for the development of products to treat diseases in which inflammation plays a role. Critical Therapeutics is undertaking a program to develop a small molecule product candidate that inhibits the inflammatory response by stimulating the alpha-7 receptor on human inflammatory cells.

*Therapeutic Opportunity*

Critical Therapeutics successful development of a product candidate targeting the alpha-7 receptor could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma, rheumatoid arthritis and Crohn s disease. Critical Therapeutics believes the previous work on the alpha-7 receptor will assist the discovery of new, peripherally acting drugs that selectively stimulate the alpha-7 receptor. Critical Therapeutics believes a drug candidate taken orally could have a strong market position against current injectable anti-TNF alpha biological therapies,

Table of Contents

particularly if it avoids the potential immunological response to therapy, which is a known risk with antibody products.

*Development Strategy*

Critical Therapeutics is currently completing preclinical evaluations of proprietary small molecule product candidates in its alpha-7 program. Critical Therapeutics has seen positive results with its molecules in animal models of allergic lung inflammation and acute lung injury, including models using alpha-7 knock-out mice. Critical Therapeutics believes the initial results support the concept that the alpha-7 receptor plays an important role in modulating the severity of inflammation in these models and that Critical Therapeutics molecules work by stimulating this receptor. Critical Therapeutics has selected both a lead and a backup molecule, and it believes both have shown promising preclinical pharmacology and non-GLP toxicology results. Critical Therapeutics moved the lead molecule into GLP toxicology evaluations in 2008. Provided the data are supportive and sufficient resources are available, Critical Therapeutics believes that an IND could be filed in 2009. Critical Therapeutics plans to seek a collaborator for its alpha-7 program to develop and commercialize possible product candidates in multiple development opportunities that may exist for this program prior to initiation of human clinical trials.

***HMGB1 Program***

Critical Therapeutics is evaluating mechanisms to prevent HMGB1 from effecting its role in inflammation-mediated diseases. HMGB1 has been identified as a potential late mediator of inflammation-induced tissue damage. Unlike other previously identified cytokines, such as interleukin-1 and TNF alpha, HMGB1 is expressed much later in the inflammatory response and persists at elevated levels in the bloodstream for a longer time period. Critical Therapeutics believes, therefore, that HMGB1 is a unique target for the development of products to treat inflammation-mediated diseases.

In 2003, Critical Therapeutics entered into an exclusive license and collaboration agreement with MedImmune to jointly develop and commercialize therapeutic products directed towards blocking the pro-inflammatory activity of HMGB1. In January 2005, Critical Therapeutics entered into a collaboration with Beckman Coulter to develop a diagnostic assay that could be used to identify which patients have elevated levels of HMGB1 and would, therefore, be most likely to respond to anti-HMGB1 therapy.

As part of the MedImmune collaboration, the research programs are currently aimed at generating antibodies that can neutralize circulating HMGB1 prior to it binding to its receptor. Fully human antibodies directed towards HMGB1, including fully human antibodies identified as part of the MedImmune collaboration, are currently in preclinical development. In December 2005, MedImmune agreed that proof of concept had been achieved for two preclinical models with human anti-HMGB1 monoclonal antibodies. These antibodies are now undergoing further evaluation with the goal of selecting candidates for use in clinical testing.

*Therapeutic Opportunity*

Critical Therapeutics believes that HMGB1 s delayed and prolonged expression offers a new target for the development of products for acute diseases that can result in multiple organ failure, including sepsis and septic shock, and acute exacerbations of chronic diseases associated with the inflammatory response mediated by cytokines, such as rheumatoid arthritis and lupus.

Sepsis is the body s systemic inflammatory response to infection or trauma. In animal models relating to septic shock, monoclonal antibodies targeting HMGB1 were successful in significantly reducing the mortality rate associated with these models. To date, limited clinical investigations have identified that patients with sepsis have elevated levels of

HMGB1 in their bloodstream, compared to normal individuals, who do not have detectable levels of HMGB1 in their bloodstream. The elevated HMGB1 levels appeared to be greatest in the patients who subsequently died as a result of their disease.

Similar treatment opportunities also exist with other diseases that include an HMGB1 component, such as rheumatoid arthritis. Elevated levels of HMGB1 have been observed in the synovial fluid in the joints of

Table of Contents

rheumatoid arthritis patients, and positive symptom responses have been achieved in animal models of rheumatoid arthritis with anti-HMGB1 therapy. Human monoclonal antibodies jointly generated by the collaboration with MedImmune have demonstrated promising activity in assays and animal models with relevance to clinical arthritis and lupus.

*Clinical Strategy*

Critical Therapeutics has generated a number of fully human antibodies that bind to HMGB1 and that are active in vitro and in vivo. A number of these antibodies have demonstrated a dose-dependent benefit on survival in a mouse model of sepsis and a reduction in clinical arthritis symptoms in mouse and rat models of arthritis. In some of these tests, the monoclonal antibodies were administered in a treatment model after disease onset, as opposed to the preventive model in which the drug is administered before disease onset.

The research phase of the collaboration with MedImmune has ended and, under the collaboration agreement, MedImmune is responsible for conducting programs necessary to advance potential product candidates into Phase I clinical trials. As of September 15, 2008, no decision to select a clinical candidate has been made.

**Collaborations**

***Zileuton Co-Promotion Agreement with DEY***

On March 13, 2007, Critical Therapeutics entered into an agreement with DEY under which Critical Therapeutics and DEY agreed to jointly co-promote ZYFLO and, after approval by the FDA, ZYFLO CR. Under the co-promotion and marketing services agreement, Critical Therapeutics granted DEY an exclusive right and license or sublicense, under patent rights controlled by Critical Therapeutics, to promote and detail ZYFLO and ZYFLO CR in the United States, together with Critical Therapeutics and its affiliates, for asthma and, subject to FDA approval, other respiratory conditions.

Both Critical Therapeutics and DEY have agreed to use diligent efforts to promote the applicable products in the United States during the term of the co-promotion agreement. In addition, DEY has agreed to provide a minimum number of details per month for ZYFLO CR in the second position to office-based physicians and other health care professionals, including a minimum number of details delivered to respiratory specialists, such as allergists and pulmonologists. Critical Therapeutics has agreed to provide a minimum number of details per month for ZYFLO CR in the first position. From 2008 through 2010, Critical Therapeutics and DEY each have agreed to contribute 50% of approved out-of-pocket promotional expenses for ZYFLO CR that are accrued or paid to third-parties. Critical Therapeutics and DEY each have agreed to contribute a minimum of $3.0 million per year for these promotional expenses. Critical Therapeutics was responsible for third-party promotional costs during 2007.

Under the co-promotion agreement, DEY paid Critical Therapeutics in 2007 a non-refundable upfront payment of $3.0 million upon signing the co-promotion agreement, non-refundable milestone payments of $4.0 million following approval by the FDA of the NDA for ZYFLO CR and $5.0 million following commercial launch of ZYFLO CR. Critical Therapeutics, in accordance with Emerging Issues Task Force, or EITF, Issue No. 02-16, *Accounting for Consideration Received from a Vendor by a Customer (Including a Reseller of the Vendor s Products),* or EITF 02-16, has deferred the $12.0 million in aggregate payments received to date and is amortizing these payments over the term of the agreement. The amortization of the upfront and milestone payments will be offset by the co-promotion fees paid to DEY for promoting ZYFLO and ZYFLO CR. Critical Therapeutics records any co-promotion fees paid to DEY and the amortization of the upfront and milestone payments as sales and marketing expenses.

Under the co-promotion agreement, Critical Therapeutics records all quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, up to $1.95 million. Critical Therapeutics pays DEY a portion of quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, in excess of $1.95 million. From the date DEY began detailing ZYFLO through the commercial launch of ZYFLO CR in September 2007, Critical Therapeutics agreed to pay DEY 70% of quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, in excess of $1.95 million. Following the commercial launch of ZYFLO CR in September 2007

through December 31, 2010, Critical Therapeutics has agreed to pay DEY 35% of quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, in excess of $1.95 million. From January 1, 2011 through December 31, 2013, Critical Therapeutics has agreed to pay DEY 20% of quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, in excess of $1.95 million. For the year ended December 31, 2007 and for the six months ended June 30, 2008, Critical Therapeutics paid $0 and $385,000, respectively, in co-promotion fees to DEY. At December 31, 2007 and June 30, 2008, Critical Therapeutics had $680,000 and $978,000, respectively, included in accrued expenses related to co-promotion fees owed to DEY.

The co-promotion agreement has a term expiring on December 31, 2013, which may be extended upon mutual agreement by the parties. Beginning September 25, 2010, either party may terminate the co-promotion agreement with six-months advance written notice. In addition, DEY has the right to terminate the co-promotion agreement with two-months prior written notice if ZYFLO CR cumulative net sales for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than $25 million. Each party has the right to terminate the co-promotion agreement upon the occurrence of a material uncured breach by the other party.

DEY has agreed not to manufacture, detail, sell, market or promote any product containing zileuton as one of the APIs for sale in the United States until the later of one year after expiration or termination of the co-promotion agreement and March 15, 2012. However, if an AB-rated generic product to ZYFLO CR is introduced, DEY would not be subject to these non-competition obligations, and DEY will have the exclusive right to market the authorized generic version of ZYFLO CR. DEY also will not be subject to these non-competition obligations if DEY terminates the co-promotion agreement either because ZYFLO CR cumulative net sales for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than $25 million or upon the occurrence of a material uncured breach by Critical Therapeutics.

During the term of the co-promotion agreement, a joint commercial committee with two members from Critical Therapeutics and two members from DEY oversees co-promotion activities under the co-promotion agreement. The co-promotion agreement provides that the joint commercial committee will make decisions by unanimous agreement, with disagreements being referred for resolution by the Chief Executive Officer of each party and further disputes being subject to non-binding mediation.

***PERFOROMIST Co-Promotion Agreement with DEY***

On June 25, 2007, Critical Therapeutics entered into a co-promotion agreement with DEY relating to PERFOROMIST, DEY s product for the treatment of COPD. Under the co-promotion agreement, DEY granted Critical Therapeutics a right and license or sublicense to promote and detail PERFOROMIST in the United States, together with DEY. The co-promotion agreement supersedes a binding letter agreement between DEY and Critical Therapeutics dated March 13, 2007 relating to the co-promotion of PERFOROMIST. On July 2, 2008, Critical Therapeutics provided notice to DEY that Critical Therapeutics had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

Both Critical Therapeutics and DEY have agreed to use diligent efforts to promote PERFOROMIST in the United States during the term of the co-promotion agreement. In addition, Critical Therapeutics has agreed to provide a minimum number of primary detail equivalents per month for PERFOROMIST to a specified group of office-based physicians and other health care professionals. Critical Therapeutics is responsible for its own sales force expenses, including the cost of promotional materials used by its sales force. Under this co-promotion agreement, DEY has agreed to pay Critical Therapeutics a co-promotion fee under a calculation based on retail sales of PERFOROMIST.

During the term of this co-promotion agreement and for a period of one year after the expiration or termination of the co-promotion agreement, Critical Therapeutics has agreed not to manufacture, detail, sell, market or promote in the

United States any product containing forms or derivatives of formoterol, or FAPI, as one of the APIs for PERFOROMIST s approved indications, other than PERFOROMIST, during the term of the co-promotion agreement. Notwithstanding the foregoing, if Critical Therapeutics signs a definitive agreement to be acquired by or merged with a third party that markets, manufactures, sells, details or

Table of Contents

promotes a product containing FAPI for sale in the United States, then, in lieu of the foregoing non-competition provision, Critical Therapeutics has agreed to specified restrictions on the activities of its sales representatives for a specified 180-day period.

If Critical Therapeutics signs a definitive agreement to be acquired by or merged with a third party that markets, manufactures, sells, details or promotes a product containing FAPI for sale in the United States, each party will have the right to terminate the co-promotion agreement with three business days advance written notice. Each party has the right to terminate the co-promotion agreement upon the occurrence of a material uncured breach by the other party.

***MedImmune Collaboration***

In July 2003, Critical Therapeutics entered into an exclusive license and collaboration agreement with MedImmune to jointly develop products directed towards HMGB1. This agreement was amended in December 2005. Under the terms of the agreement, Critical Therapeutics granted MedImmune an exclusive worldwide license, under patent rights and know-how controlled by Critical Therapeutics, to make, use and sell products, including antibodies, that bind to, inhibit or inactivate HMGB1 and are used in the treatment or prevention, but not the diagnosis, of diseases, disorders and medical conditions.

Critical Therapeutics and MedImmune determine the extent of the collaboration on research and development matters each year upon the renewal of a rolling three-year research plan. Critical Therapeutics is currently working with MedImmune to evaluate the potential of a series of fully human monoclonal antibodies as agents for development as therapeutic antibodies to enable them to enter clinical development. Under the terms of the agreement, MedImmune agreed to fund and expend efforts to research and develop at least one HMGB1-inhibiting product for two indications through specified clinical phases.

Under the agreement, Critical Therapeutics was required to perform certain research activities under an agreed upon research plan that ended in 2007. During the term of the research plan, Critical Therapeutics received research funding from MedImmune based on the number of full-time equivalents employed by Critical Therapeutics for purposes of executing the research plan. All payments made to Critical Therapeutics under the agreement are non-refundable. In connection with the research portion of the agreement, Critical Therapeutics recorded $17.9 million in revenue over the 47-month term. The payments included $12.5 million in upfront license fees and research funding, which was paid in two installments of $10.0 million in late 2003 and $2.5 million in early 2004; $1.3 million for the achievement of a specified research milestone in early 2005; and $4.1 million in payments for research work performed by Critical Therapeutics. No performance is required of Critical Therapeutics subsequent to the research period and MedImmune is responsible for subsequent product development and commercialization. Under the agreement, Critical Therapeutics may receive, subject to the terms and conditions of the agreement, other payments upon the achievement of development and commercialization milestones by MedImmune up to a maximum of $124.0 million, after taking into account payments that Critical Therapeutics is obligated to make to The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute), or The Feinstein Institute. Critical Therapeutics has not recorded and will not record these future development and commercialization milestones until they are achieved. MedImmune also has agreed to pay royalties to Critical Therapeutics based upon net sales by MedImmune of licensed products resulting from the collaboration. MedImmune s obligation to pay Critical Therapeutics royalties continues on a product-by-product and country-by-country basis until the later of 10 years from the first commercial sale of a licensed product in each country and the expiration of the patent rights covering the product in that country. Critical Therapeutics is obligated to pay a portion of any milestone payments or royalties Critical Therapeutics receives from MedImmune to The Feinstein Institute, which initially licensed to Critical Therapeutics patent rights and know-how related to HMGB1. In connection with entering into the collaboration agreement, an affiliate of MedImmune purchased an aggregate of $15.0 million of Critical Therapeutics series B convertible preferred stock in October 2003 and March 2004, which converted into 2,857,142 shares of Critical

Therapeutics common stock in June 2004 in connection with Critical Therapeutics initial public offering.

In December 2005, MedImmune agreed that the collaboration demonstrated proof of concept in two preclinical disease models with human HMGB1 monoclonal antibodies. As a result, MedImmune made a $1.25 million milestone payment to Critical Therapeutics. In December 2005, MedImmune agreed to fund an

Table of Contents

additional $1.0 million of research work performed by Critical Therapeutics full-time employees in 2006. In March 2007, MedImmune agreed to fund an additional $125,000 of research work performed by Critical Therapeutics full-time employees in 2007.

Critical Therapeutics worked exclusively with MedImmune in the research and development of HMGB1-inhibiting products through the first half of 2007. Since then, MedImmune has assumed full responsibility for all of the research and development efforts related to the program. Under the terms of the agreement, MedImmune s license to commercialize HMGB1-inhibiting products generally excludes Critical Therapeutics from manufacturing, promoting or selling the licensed products. However, Critical Therapeutics has the option to co-promote in the United States the first product for the first indication approved in the United States, for which Critical Therapeutics must pay a portion of the ongoing development costs and will receive a proportion of the profits in lieu of royalties that would otherwise be owed to Critical Therapeutics. MedImmune has the right to terminate Critical Therapeutics co-promotion option in connection with a change of control of Critical Therapeutics. MedImmune has informed Critical Therapeutics that it is terminating Critical Therapeutics co-promotion rights in connection with the merger with Cornerstone.

MedImmune has the right to terminate the agreement at any time on six-months written notice. Each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. Under specified conditions, Critical Therapeutics or MedImmune may have certain payment or royalty obligations after the termination of the agreement.

***Beckman Coulter Collaboration***

In January 2005, Critical Therapeutics entered into a license agreement with Beckman Coulter relating to the development of diagnostic products for measuring HMGB1. Under the terms of the agreement, Critical Therapeutics granted to Beckman Coulter and its affiliates an exclusive worldwide license, under patent rights and know-how controlled by Critical Therapeutics relating to the use of HMGB1 and its antibodies in diagnostics, to evaluate, develop, make, use and sell a kit or assemblage of reagents for measuring HMGB1 that utilizes one or more monoclonal antibodies to HMGB1 developed by Critical Therapeutics or on its behalf.

In consideration for the license, Beckman Coulter paid Critical Therapeutics a product evaluation license fee of $250,000. Beckman Coulter exercised its development option under the license agreement in December 2006 and paid Critical Therapeutics $400,000 in January 2007. Under the agreement, Critical Therapeutics may also receive additional aggregate license fees of up to $450,000 upon the achievement of the first commercial sale of a licensed product. Beckman Coulter also agreed to pay Critical Therapeutics royalties based on net sales of licensed products by Beckman Coulter and its affiliates. Beckman Coulter has the right to grant sublicenses under the license, subject to Critical Therapeutics written consent, which Critical Therapeutics has agreed not to unreasonably withhold. In addition, Beckman Coulter agreed to pay Critical Therapeutics a percentage of any license fees, milestone payments or royalties actually received by Beckman Coulter from its sublicensees.

Beckman Coulter has the right to terminate the license agreement at any time on 90-days written notice. Each party has the right to terminate the license agreement upon the occurrence of a material uncured breach by the other party.

**Development**

As of September 15, 2008, Critical Therapeutics had two employees engaged in development and regulatory activities. During the six months ended June 30, 2008 and the fiscal years ended December 31, 2007, 2006 and 2005, research and development expenses were $6.9 million, $21.7 million, $26.9 million and $30.0 million, respectively.

**Sales and Marketing**

Critical Therapeutics has a respiratory sales force of approximately 26 representatives as of September 15, 2008, who are focused on promoting ZYFLO CR and PERFOROMIST to prescribing physicians within major markets across the United States. Under Critical Therapeutics co-promotion agreement with DEY, DEY has

Table of Contents

agreed to provide a minimum number of details per month for in the second position to office-based physicians and other health care professionals, including a minimum number of details delivered to respiratory specialists, such as allergists and pulmonologists. Critical Therapeutics has agreed to provide a minimum number of details per month for ZYFLO CR in the first position. In addition, under the co-promotion agreement with DEY for PERFOROMIST, Critical Therapeutics has agreed to provide a minimum number of primary detail equivalents per month for PERFOROMIST to a specified group of office-based physicians and other health care professionals. On July 2, 2008, Critical Therapeutics provided notice to DEY that Critical Therapeutics had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

Critical Therapeutics is focusing its sales and marketing efforts for ZYFLO CR on respiratory specialists who treat asthma, including allergists and pulmonologists, and primary care physicians who treat large numbers of asthma patients. Critical Therapeutics believes that within this targeted group there are approximately 100 to 200 national and regional scientific and clinical key opinion leaders who serve to influence the direction of the diagnosis and treatment of asthma through their publications and presentations at scientific and clinical medical conferences. Critical Therapeutics also expects to focus its medical outreach efforts on local, clinically-based key opinion leaders.

Given the importance of the scientific and clinical key opinion leaders, Critical Therapeutics is directing its scientific message and support to help educate and inform key opinion leaders regarding the scientific rationale and clinical data that support its commercialization strategy. Critical Therapeutics has entered into consulting arrangements with a number of key opinion leaders who provide expert advice to it.

In June 2007, the NHLBI released an updated version of the Guidelines for the Diagnosis and Management of Asthma. In these guidelines, zileuton is specifically mentioned in steps three and four in the treatment spectrum as an alternative option in the treatment of asthma. This is the first time zileuton has been mentioned in these guidelines, and Critical Therapeutics believes this may provide additional scientific credibility to ZYFLO CR in the marketplace. In addition to the changes in the recommended treatment protocol for asthma, the updated guidelines continue to support the transition to the discussion of asthmatic patients in terms of their level of control rather than their severity level.

**Manufacturing and Supply**

Critical Therapeutics has limited experience in manufacturing its products and product candidates. Critical Therapeutics currently outsources the manufacturing of ZYFLO CR and ZYFLO for commercial sale and the manufacturing of its product candidates for use in clinical trials to qualified third parties and intends to continue to rely on contract manufacturing from third parties to supply products for both clinical use and commercial sale.

In January 2008, Critical Therapeutics requested and received from the FDA a waiver from the requirement to provide six-months notice to cease manufacturing ZYFLO. In February 2008, Critical Therapeutics stopped the manufacture and supply of ZYFLO to the market. In March 2008, Critical Therapeutics began to experience supply chain issues with ZYFLO CR. In the quarter ended June 30, 2008, Critical Therapeutics recorded an inventory reserve with respect to an aggregate of eight batches of ZYFLO CR that could not be released into Critical Therapeutics commercial supply chain, consisting of one batch of ZYFLO CR that did not meet Critical Therapeutics product release specifications and an additional seven batches of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. In the quarters ended December 31, 2007 and March 31, 2008, Critical Therapeutics recorded inventory reserves with respect to an aggregate of eight batches of ZYFLO CR that could not be released into Critical Therapeutics commercial supply chain because they did not meet Critical Therapeutics product release specifications. In conjunction with Critical Therapeutics three third-party manufacturers for zileuton API, tablet cores and coating and release, Critical Therapeutics has initiated an investigation to determine the cause of this issue, but the investigation is ongoing and is not yet complete. Critical

Therapeutics has incurred and expects to continue to incur significant costs in connection with its investigation. To date, the investigation has not identified a clear source of the issue. In August and September

Table of Contents

2008, Critical Therapeutics released and made available for shipment to wholesale distributors an aggregate of six batches of finished ZYFLO CR tablets that met its product release specifications. Critical Therapeutics is currently unable to accurately assess the timing and quantity of future batches of ZYFLO CR, if any, that may be released for commercial supply. If not corrected, the ongoing supply chain difficulties could prevent Critical Therapeutics from supplying any further product to its wholesale distributors. Based on its current level of sales and the release of the six batches of ZYFLO CR in August and September 2008, Critical Therapeutics estimates that wholesale distributors and retail pharmacies will have a sufficient inventory of ZYFLO CR to continue to provide product to patients through the fourth quarter of 2008.

In April 2008, Critical Therapeutics began to reinitiate manufacture of ZYFLO in order to have a supply of ZYFLO available to reinitiate marketing and supply of ZYFLO to the market given the supply chain issues being experienced for ZYFLO CR. In September 2008, Critical Therapeutics resumed distribution of ZYFLO to help manage any potential impact to patients of supply chain issues for ZYFLO CR.

Critical Therapeutics has established the following manufacturing arrangements for zileuton.

***Shasun Pharma Solutions***

Critical Therapeutics originally contracted with Rhodia Pharma Solutions Ltd. for the commercial production of the zileuton API. On March 31, 2006, Rhodia SA, the parent company of Rhodia Pharma Solutions, sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhodia SA assigned Critical Therapeutics contract with Rhodia Pharma Solutions Ltd. to Shasun. Under Critical Therapeutics agreement with Shasun, as amended, Shasun has agreed to manufacture Critical Therapeutics commercial supplies of API, subject to specified limitations, through the earlier of the date on which Critical Therapeutics has purchased a specified amount of the API for zileuton and December 31, 2010. Critical Therapeutics has committed to purchase a minimum amount of zileuton API from Shasun of $2.0 million in 2008 and $2.0 million in 2009, although Critical Therapeutics has the right to reduce by $1.3 million the amount of zileuton API it must purchase in 2009 by providing written notice to Shasun no later than December 31, 2008. The API purchased from Shasun currently has a shelf-life of 36 months. The agreement will automatically extend for successive one-year periods after December 31, 2010, unless Shasun provides Critical Therapeutics with 18-months prior written notice of cancellation. Critical Therapeutics has the right to terminate the agreement upon 12-months prior written notice for any reason, provided that Critical Therapeutics may not cancel prior to the earlier of December 31, 2010 or the date on which it has purchased a specified amount of the API. Critical Therapeutics also has the right to terminate the agreement upon six-months prior written notice if it terminates its plans to commercialize zileuton for all therapeutic indications. In addition, Critical Therapeutics has the right to terminate the agreement upon 30-days prior written notice if any governmental agency takes any action, or raises any objection, that prevents Critical Therapeutics from importing, exporting, or selling zileuton products or the API. If Critical Therapeutics exercises its right to terminate the agreement prior to its scheduled expiration, Critical Therapeutics is obligated to reimburse Shasun for specified raw material and out-of-pocket costs. In addition, if Critical Therapeutics exercises its right to terminate the agreement due to termination of Critical Therapeutics plans to commercialize zileuton for all therapeutic indications, then Critical Therapeutics is also obligated to pay Shasun for all API manufactured by Shasun through that date. Furthermore, each party has the right to immediately terminate the agreement for cause, including a material uncured default by the other party.

***Jagotec***

Critical Therapeutics has contracted with Jagotec for the manufacture and supply of bulk, uncoated tablets of ZYFLO CR for Critical Therapeutics for commercial sale. Critical Therapeutics has agreed to purchase minimum quantities of ZYFLO CR during each 12-month period for the first five years following marketing approval of ZYFLO CR by the

FDA. For the term of the contract, Critical Therapeutics has agreed to purchase specified amounts of its requirements for ZYFLO CR from Jagotec. Critical Therapeutics has committed to purchase a minimum of 20 million ZYFLO CR tablet cores from Jagotec in each of the four 12-month periods starting May 30, 2008. The commercial manufacturing agreement has an initial term of five

Table of Contents

years beginning on May 22, 2007, and will automatically continue thereafter, unless Critical Therapeutics provides Jagotec with 24-months prior written notice of termination or Jagotec provides Critical Therapeutics with 36-months prior written notice of termination. In addition, Critical Therapeutics has the right to terminate the agreement upon 30-days prior written notice in the event any governmental agency takes any action, or raises any objection, that prevents Critical Therapeutics from importing, exporting or selling ZYFLO CR. Critical Therapeutics also may terminate the agreement upon six-months advance notice in the event that an AB-rated generic pharmaceutical product containing zileuton is introduced in the United States and Critical Therapeutics determines to permanently cease commercialization of ZYFLO CR. Likewise, Critical Therapeutics may terminate the agreement upon 12-months advance notice if it intends to discontinue commercializing ZYFLO CR tablets. Furthermore, each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. In the event either party terminates the agreement, Critical Therapeutics agreed to purchase quantities of ZYFLO CR tablets that are subject to binding forecasts.

***Patheon Pharmaceuticals***

Critical Therapeutics has contracted with Patheon to coat, conduct quality control and quality assurance and stability testing and package commercial supplies of ZYFLO CR. Under this agreement, Critical Therapeutics is responsible for supplying uncoated ZYFLO CR tablets to Patheon. Critical Therapeutics has agreed to purchase at least 50% of its requirements for such manufacturing services for ZYFLO CR for sale in the United States from Patheon each year during the term of this agreement. This agreement has an initial term of three years beginning May 9, 2007, and will automatically continue for successive one-year periods thereafter, unless Critical Therapeutics provides Patheon with 12-months prior written notice of termination or Patheon provides Critical Therapeutics with 18-months prior written notice of termination. In addition, Critical Therapeutics has the right to terminate this agreement upon 30-days prior written notice in the event that any governmental agency takes any action, or raises any objection, that prevents Critical Therapeutics from importing, exporting, purchasing or selling ZYFLO CR. Critical Therapeutics also has the right to terminate this agreement upon 90-days prior written notice if an AB-rated generic product to ZYFLO CR is introduced in the United States. If Critical Therapeutics provides six-months advance notice that it intends to discontinue commercializing ZYFLO CR, Critical Therapeutics will not be required to purchase any additional quantities of ZYFLO CR finished tablets from Patheon, provided that Critical Therapeutics pays Patheon for a portion of specified fees and expenses associated with orders Critical Therapeutics previously placed. Patheon has the right to terminate this agreement if Critical Therapeutics assigns any of Critical Therapeutics rights under the agreement to an assignee other than a purchaser or merger partner that, in Patheon s reasonable opinion, is not a credit worthy substitute for Critical Therapeutics, is a competitor of Patheon or is an entity with whom Patheon has had prior unsatisfactory business relations. Furthermore, each party has the right to terminate this agreement upon the occurrence of a material uncured breach by the other party. If this agreement expires or is terminated for any reason, Critical Therapeutics has agreed to take delivery of and pay for undelivered quantities of ZYFLO CR that it previously ordered, purchase, at cost, Patheon s inventory of ZYFLO CR maintained in contemplation of filling orders previously placed by Critical Therapeutics and pay the purchase price for components ordered by Patheon from suppliers in reliance on orders Critical Therapeutics previously placed.

Critical Therapeutics has contracted with Patheon for the manufacture of commercial supplies of ZYFLO immediate release tablets. Critical Therapeutics has agreed to purchase at least 50% of its commercial supplies of ZYFLO immediate-release tablets for sale in the United States from Patheon each year for the term of the agreement. The commercial manufacturing agreement has an initial term of three years beginning on September 15, 2005, and will automatically continue for successive one-year periods thereafter, unless Critical Therapeutics provides Patheon with 12-months prior written notice of termination or Patheon provides Critical Therapeutics with 18-months prior written notice of termination. In addition, Critical Therapeutics has the right to terminate the agreement upon 30-days prior written notice in the event any governmental agency takes any action, or raises any objection, that prevents it from importing, exporting, purchasing or selling ZYFLO. If Critical Therapeutics provides six-months advance notice that

it intends to discontinue commercializing ZYFLO, Critical Therapeutics will not be required to purchase any additional quantities of

Table of Contents

ZYFLO immediate release tablets, provided that it must pay Patheon for a portion of specified fees and expenses associated with orders previously placed by Critical Therapeutics. Furthermore, each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. If the agreement expires or is terminated for any reason, Critical Therapeutics has agreed to take delivery of and pay for undelivered quantities of ZYFLO that it previously ordered, purchase, at cost, Patheon s inventory of ZYFLO maintained in contemplation of filling orders previously placed by Critical Therapeutics and pay the purchase price for components of the ZYFLO immediate release tablets ordered by Patheon from suppliers in reliance on orders previously placed by Critical Therapeutics.

***CyDex***

Critical Therapeutics has entered into a license and supply agreement with CyDex, Inc., or CyDex, relating to Critical Therapeutics clinical development and planned commercialization of zileuton injection. Under this agreement, CyDex granted to Critical Therapeutics a worldwide, exclusive license, under patent rights controlled by CyDex relating to CyDex s CAPTISOL® drug enablement technology, for use with zileuton, under which Critical Therapeutics can develop, make, use and sell zileuton combined with or formulated using CAPTISOL in an injectable dosage form for ultimate use in humans. In addition, CyDex granted Critical Therapeutics a worldwide, non-exclusive license to utilize CyDex s toxicology and safety and other relevant scientific data, relating to CAPTISOL, to develop, make, use and sell in combination with zileuton. Under this agreement, Critical Therapeutics agreed that it and its affiliates and sublicensees will purchase CAPTISOL exclusively from CyDex, and CyDex has agreed to supply 100% of Critical Therapeutics and its affiliates and sublicensees requirements for CAPTISOL up to a specified amount per year during the term of the agreement.

In consideration for the licenses granted to Critical Therapeutics under the agreement, Critical Therapeutics paid CyDex an initial license fee of $50,000 and agreed to make aggregate milestone payments of up to $2.9 million upon the achievement of specified development, regulatory and commercialization milestones for the combined product. In addition, Critical Therapeutics agreed to pay royalties to CyDex based on net sales of the combined product by Critical Therapeutics and its affiliates and licensees. Critical Therapeutics obligation to pay royalties expires, with respect to each country in which the combined product is commercialized, upon the later of the expiration of the last relevant patent that claims CAPTISOL in such country or ten years from the first commercial sale of the combined product in such country.

The term of the agreement expires upon the expiration of Critical Therapeutics obligation to pay royalties. CyDex has the right to terminate the agreement upon the occurrence of an uncured breach by Critical Therapeutics. Critical Therapeutics has the right to terminate the agreement at any time upon 75-days prior written notice.

***Other***

Critical Therapeutics expects to need to enter into manufacturing arrangements with third parties for the manufacture of Critical Therapeutics other product candidates for clinical use. For example, Critical Therapeutics will need to enter into arrangements for the manufacture of product candidates for clinical trials in its alpha-7 program. Under Critical Therapeutics collaboration agreement with MedImmune, MedImmune would be responsible for manufacturing any biologic products that result from the HMGB1 program.

**Distribution Network**

Critical Therapeutics currently relies on third parties to distribute ZYFLO CR and ZYFLO to pharmacies. Critical Therapeutics has contracted with ICS, a third-party logistics company, to warehouse ZYFLO CR and ZYFLO and distribute it to three primary wholesalers, AmerisourceBergen Corporation, Cardinal Health and McKesson

Corporation, and a number of smaller wholesalers. The wholesalers, in turn, distribute it to chain and independent pharmacies. ICS is Critical Therapeutics exclusive supplier of commercial distribution logistics services.

Table of Contents

Critical Therapeutics relies on Phoenix to distribute samples of ZYFLO CR and ZYFLO to Critical Therapeutics sales representatives, who in turn distribute samples to physicians and other prescribers who are authorized under state law to receive and dispense samples.

This distribution network requires significant coordination with Critical Therapeutics supply chain, sales and marketing and finance organizations. Critical Therapeutics does not have its own warehouse or distribution capabilities. Critical Therapeutics does not intend to establish these functions on its own in the foreseeable future.

**License and Royalty Agreements**

Critical Therapeutics has entered into a number of license agreements under which it has licensed intellectual property and other rights needed to develop its products or under which Critical Therapeutics has licensed intellectual property and other rights to third parties, including the license agreements summarized below.

***Abbott***

In December 2003, Critical Therapeutics acquired an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell controlled-release and injectable formulations of zileuton for all clinical indications, except for the treatment of children under age seven and use in cardiovascular and vascular devices. This license included an exclusive sublicense of Abbott s rights in proprietary controlled-release technology originally licensed to Abbott by Jagotec. In consideration for the license, Critical Therapeutics paid Abbott an initial $1.5 million license fee and agreed to make aggregate milestone payments of up to $13.0 million to Abbott upon the achievement of various development and commercialization milestones, including the completion of the technology transfer from Abbott to Critical Therapeutics, filing and approval of a product in the United States and specified minimum net sales of licensed products. In addition, Critical Therapeutics agreed to pay royalties to Abbott based on net sales of licensed products by Critical Therapeutics, its affiliates and sublicensees. Critical Therapeutics obligation to pay royalties continues on a country-by-country basis for a period of ten years from the first commercial sale of a licensed product in each country. Upon the expiration of Critical Therapeutics obligation to pay royalties for licensed products in a given country, the license will become perpetual, irrevocable and fully paid up with respect to licensed products in that country. If Critical Therapeutics decides to sublicense rights under the license, Critical Therapeutics must first enter into good faith negotiations with Abbott for the commercialization rights to the licensed product. Abbott waived its right of first negotiation with respect to Critical Therapeutics co-promotion arrangement with DEY for ZYFLO CR. Each party has the right to terminate the license upon the occurrence of a material uncured breach by the other party. Critical Therapeutics also has the right to terminate the license at any time upon 60-days notice to Abbott and payment of a termination fee. Through December 31, 2007, Critical Therapeutics has paid milestone and license payments totaling $6.5 million to Abbott under this agreement. In addition, after the FDA approved the NDA for ZYFLO CR in May 2007, Critical Therapeutics accrued $2.8 million in milestone payments it owes to Abbott on the first and second anniversary of the approval of the ZYFLO CR NDA.

In March 2004, Critical Therapeutics acquired from Abbott the U.S. trademark ZYFLO® and an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell the immediate-release formulation of zileuton for all clinical indications. In consideration for the license and the trademark, Critical Therapeutics paid Abbott an initial fee of $500,000 and a milestone payment of $750,000 upon approval of the sNDA, which Critical Therapeutics paid in October 2005, and Critical Therapeutics agreed to pay royalties based upon net sales of licensed products by Critical Therapeutics, its affiliates and sublicensees. Critical Therapeutics obligation to pay royalties continues on a country-by-country basis for a period of ten years from the first commercial sale of a licensed product in each country. Upon the expiration of Critical Therapeutics obligation to pay royalties in a given country, the license will become perpetual, irrevocable and fully paid up with respect to licensed products in that country. Each party has the right to terminate the license upon the occurrence of a material uncured breach by the

other party.

Table of Contents

***Baxter***

In June 2004, Critical Therapeutics entered into an agreement with Baxter Healthcare Corporation to conduct feasibility studies to analyze the various properties of zileuton and determine the most suitable technologies for the development of an injectable formulation of zileuton. In the event that Critical Therapeutics chooses to pursue the commercialization of a specified injectable formulation developed by Baxter that is based on the formulation technology of a third party, Baxter granted Critical Therapeutics an exclusive, worldwide, non-revocable license to the formulation intellectual property in return for Critical Therapeutics agreement to pay Baxter royalties based on net sales of that formulation. However, Critical Therapeutics would need to finalize the license agreement to document such license based on the agreed financial terms, which Critical Therapeutics may not be able to negotiate on favorable terms, if at all. It is also possible that Critical Therapeutics may instead determine to pursue the commercialization of an injectable formulation developed by Baxter based on its own proprietary formulation technology. If Critical Therapeutics determines to do so, Critical Therapeutics would need to license from Baxter rights to that injectable formulation. In that case, Critical Therapeutics may not be able to negotiate a license agreement on favorable terms, if at all. Furthermore, although Baxter has filed two U.S. patent applications, one for the specified injectable formulation developed by Baxter based on the formulation technology of a third party and another for an injectable formulation developed by Baxter based on its own proprietary formulation technology, neither of these patent applications may result in issued patents.

***The Feinstein Institute***

In July 2001, Critical Therapeutics acquired from The Feinstein Institute an exclusive worldwide license, under patent rights and know-how controlled by The Feinstein Institute relating to HMGB1, to make, use and sell products covered by the licensed patent rights and know-how. The Feinstein Institute retained the right to make and use the licensed products in its own laboratories solely for non-commercial, scientific purposes and non-commercial research. In consideration for the license, Critical Therapeutics paid an initial license fee of $100,000. Critical Therapeutics also agreed to make milestone payments to The Feinstein Institute of up to $275,000 for the first product covered by the licensed patent rights and an additional $100,000 for each additional distinguishable product covered by the licensed patent rights, up to $137,500 for the first product covered by the licensed know-how and not the licensed patent rights and an additional $50,000 for each additional distinguishable product covered by the licensed know-how and not the licensed patent rights, in each case upon the achievement of specified development and regulatory milestones for the applicable licensed product. In addition, Critical Therapeutics agreed to pay The Feinstein Institute royalties based on net sales of licensed products by Critical Therapeutics and its affiliates until the later of ten years from the first commercial sale of each licensed product in a given country and the expiration of the patent rights covering the licensed product in that country. Critical Therapeutics agreed to pay minimum annual royalties to The Feinstein Institute beginning in July 2007 regardless of whether Critical Therapeutics sells any licensed products. Critical Therapeutics paid The Feinstein Institute $15,000 for minimum royalties in 2007. Critical Therapeutics also agreed to pay The Feinstein Institute fees if Critical Therapeutics sublicenses its rights under the licensed patent rights and know-how. At December 31, 2007, Critical Therapeutics accrued $13,000 owed to The Feinstein Institute in accordance with this agreement. Each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party.

Critical Therapeutics also has entered into two sponsored research and license agreements with The Feinstein Institute. In July 2001, Critical Therapeutics entered into a sponsored research and license agreement with The Feinstein Institute under which, as amended, Critical Therapeutics paid The Feinstein Institute $200,000 annually until June 2006 to sponsor research activities at The Feinstein Institute to identify inhibitors and antagonists of HMGB1 and related proteins, including antibodies. In January 2003, Critical Therapeutics entered into a sponsored research and license agreement with The Feinstein Institute under which, as amended, Critical Therapeutics agreed to pay The Feinstein Institute to sponsor research activities at The Feinstein Institute in the field of cholinergic anti-inflammatory

technology. Critical Therapeutics paid the Feinstein Institute $200,000 annually until January 2006 and $150,000 in 2006 and $120,000 in 2007 for this sponsored research. Any future research terms under either of these agreements are subject to agreement between The

Table of Contents

Feinstein Institute and Critical Therapeutics. Under the terms of these agreements, Critical Therapeutics acquired an exclusive worldwide license to make, use and sell products covered by the patent rights and know-how arising from the sponsored research. The Feinstein Institute retained the right under each of these agreements to make and use the licensed products in its own laboratories solely for non-commercial, scientific purposes and non-commercial research. Each party has the right to terminate each agreement upon the occurrence of a material uncured breach of that agreement by the other party.

In connection with the July 2001 sponsored research and license agreement, Critical Therapeutics issued The Feinstein Institute 27,259 shares of Critical Therapeutics common stock and agreed to make milestone payments to The Feinstein Institute of $200,000 for the first product covered by the licensed patent rights, and an additional $100,000 for each additional distinguishable product covered by the licensed patent rights, $100,000 for the first product covered by the licensed know-how and not the licensed patent rights and an additional $50,000 for each additional distinguishable product covered by the licensed know-how and not the licensed patent rights, in each case upon the achievement of specified development and regulatory approval milestones with respect to the applicable licensed product. In connection with the January 2003 sponsored research and license agreement, Critical Therapeutics paid The Feinstein Institute an initial license fee of $175,000 and agreed to pay additional amounts in connection with the filing of any U.S. patent application or issuance of a U.S. patent relating to the field of cholinergic anti-inflammatory technology. Critical Therapeutics also agreed to make aggregate milestone payments to The Feinstein Institute of up to $1.5 million in both cash and shares of Critical Therapeutics common stock upon the achievement of specified development and regulatory approval milestones with respect to any licensed product. In addition, under each of these agreements, Critical Therapeutics agreed to pay The Feinstein Institute royalties based on net sales of a licensed product by Critical Therapeutics and its affiliates until the later of ten years from the first commercial sale of licensed products in a given country and the expiration of the patent rights covering the licensed product in that country. Under the January 2003 sponsored research and license agreement, Critical Therapeutics agreed to pay minimum annual royalties to The Feinstein Institute beginning in the first year after termination of research activities regardless of whether Critical Therapeutics sells any licensed products. At December 31, 2007, Critical Therapeutics owed $30,000 to The Feinstein Institute in accordance with the January 2003 agreement.

Critical Therapeutics also agreed to pay The Feinstein Institute certain fees if Critical Therapeutics sublicenses its rights under the licensed patent rights and know-how under either agreement. In connection with Critical Therapeutics sublicenses to MedImmune and Beckman Coulter of Critical Therapeutics rights with respect to HMGB1, Critical Therapeutics paid The Feinstein Institute $2.5 million and issued to The Feinstein Institute 66,666 shares of Critical Therapeutics common stock. In connection with Critical Therapeutics January 2007 sublicense to SetPoint of Critical Therapeutics rights with respect to vagus nerve stimulation, Critical Therapeutics has paid The Feinstein Institute $100,000 and arranged for the issuance by SetPoint to The Feinstein Institute of 100,000 shares of junior preferred stock of SetPoint.

***Jagotec AG***

In December 2003, Critical Therapeutics entered into an agreement with Jagotec under which Jagotec consented to Abbott s sublicense to Critical Therapeutics of rights to make, use and sell ZYFLO CR covered by Jagotec s patent rights and know-how. Under the terms of the agreement, Jagotec also agreed to manufacture ZYFLO CR for clinical trials, regulatory review and, upon FDA approval and subject to negotiating a manufacturing agreement, commercial sale. In consideration for Jagotec s prior work associated with the licensed patent rights and know-how, Critical Therapeutics paid Jagotec an upfront fee of $750,000. Critical Therapeutics also agreed to make aggregate milestone payments to Jagotec of up to $6.6 million upon the achievement of various development and commercialization milestones. Through December 31, 2007, Critical Therapeutics has made milestone payments totaling $3.0 million to Jagotec under this agreement. In addition, after the FDA approved the NDA for ZYFLO CR in May 2007, Critical Therapeutics accrued an additional $699,000 in milestone payments it owes to Jagotec on the first and second

anniversary of the approval of the NDA for ZYFLO CR. In addition, Critical Therapeutics agreed to pay royalties to Jagotec based upon net sales of the product by Critical Therapeutics and its affiliates. Critical Therapeutics also agreed

Table of Contents

to pay royalties to Jagotec under the license agreement between Jagotec and Abbott based upon net sales of the product by Critical Therapeutics and its affiliates. In addition, Critical Therapeutics agreed to pay Jagotec fees if Critical Therapeutics sublicenses its rights under the licensed patent rights and know-how. In 2005, Jagotec agreed to allow Critical Therapeutics to sublicense its rights to Patheon to permit Patheon to manufacture a portion of Critical Therapeutics annual requirements for ZYFLO CR tablets. Each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party.

***SetPoint***

In January 2007, Critical Therapeutics entered into an exclusive license agreement with SetPoint under which Critical Therapeutics granted to SetPoint an exclusive worldwide license under patent rights and know-how controlled by Critical Therapeutics relating to the stimulation of the vagus nerve to make, use and sell products and methods covered by the licensed patent rights and know-how in the licensed field. The licensed field includes mechanical and electrical stimulation of the vagus nerve and excludes pharmacological modulation of a cholinergic receptor, including the alpha-7 receptor. In consideration for the license, SetPoint paid Critical Therapeutics an initial license fee of $400,000 in cash after taking into account payments that Critical Therapeutics is obligated to make to The Feinstein Institute. In addition, in connection with SetPoint s first financing, SetPoint issued to Critical Therapeutics a number of shares of junior preferred stock of SetPoint equal to the number of shares of preferred stock that could be purchased for $400,000 in such financing after taking into account payments that Critical Therapeutics is obligated to make to The Feinstein Institute. The junior preferred stock issued to Critical Therapeutics had a liquidation preference subordinate to the preferred stock issued in such financing. In March 2008, Critical Therapeutics sold these 400,000 shares of junior preferred stock to two investors, which had participated in SetPoint s first financing, for an aggregate purchase price of $400,000. The purchase price is subject to adjustment if these investors sell or receive consideration for these shares of junior preferred stock pursuant to an acquisition of SetPoint prior to February 1, 2009 at a price per share greater than they paid Critical Therapeutics.

Under this license agreement, SetPoint also agreed to:

- make a one-time milestone payment to Critical Therapeutics of $1.0 million upon the achievement of all regulatory approvals from the FDA or any foreign counterpart agency required for the marketing and sale in the applicable country of any product or method covered by the licensed patent rights;

- pay Critical Therapeutics royalties based on net sales of licensed products and methods by SetPoint and its affiliates until the expiration of the patent rights covering the licensed product or method in the country of actual or intended use; and

- pay Critical Therapeutics a percentage of any royalties, fees and payments actually received from third parties, with limited exceptions, in connection with sublicenses by SetPoint of its rights under the licensed patent rights and know-how.

The patent rights and know-how licensed by Critical Therapeutics to SetPoint include patent rights and know-how arising from research conducted by The Feinstein Institute under the sponsored research and license agreement, as amended, that Critical Therapeutics entered into with The Feinstein Institute in January 2003.

Under this license agreement, SetPoint agreed to be responsible for specified obligations Critical Therapeutics owes to The Feinstein Institute pursuant to Critical Therapeutics sponsored research and license agreement. SetPoint agreed to financially support sponsored research under the sponsored research and license agreement to the extent that the sponsored research is in the licensed field under the SetPoint license agreement. SetPoint also agreed to reimburse Critical Therapeutics for a portion of:

amounts payable to The Feinstein Institute in connection with the filing of any U.S. patent application or issuance of a U.S. patent relating to the field of cholinergic anti-inflammatory technology; and

minimum annual royalties payable to The Feinstein Institute beginning in the first year after termination of research activities under the sponsored research agreement.

Table of Contents

Each party has the right to terminate the license agreement upon the occurrence of a material uncured default by the other party. SetPoint has the right to terminate the SetPoint license agreement at any time on 90-days prior written notice to Critical Therapeutics.

Two of Critical Therapeutics co-founders, Kevin J. Tracey, M.D. and H. Shaw Warren, M.D., are founders of SetPoint. Dr. Warren served as a member of the Critical Therapeutics Board of Directors until October 2006. Dr. Tracey is a member of the medical staff at The Feinstein Institute. In addition, Critical Therapeutics is a party to a consulting agreement with Dr. Tracey that terminates on December 31, 2009. Furthermore, Critical Therapeutics was previously a party to a consulting agreement with Dr. Warren that terminated on January 1, 2008. Under Critical Therapeutics consulting agreement with Dr. Tracey, Critical Therapeutics agreed to pay certain royalties to Dr. Tracey in connection with selling or sublicensing certain licensed alpha-7 products as defined in the agreement.

**Proprietary Rights**

Critical Therapeutics success depends in part on its ability to obtain and maintain proprietary protection for its product candidates, technology and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing Critical Therapeutics proprietary rights. Critical Therapeutics policy is to seek to protect its proprietary position by, among other methods, filing U.S. and foreign patent applications related to its proprietary technology, inventions and improvements that are important to the development of its business and obtaining, where possible, assignment of invention agreements from employees and consultants. Critical Therapeutics also relies on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain its proprietary position.

As of September 15, 2008, Critical Therapeutics owns or exclusively licenses for one or more indications or formulations a total of 16 issued U.S. patents, 50 issued foreign patents, 22 pending U.S. patent applications and 60 pending foreign patent applications consisting of:

| | U.S. | | Foreign | | Program |
|---|---|---|---|---|---|
| | **Issued** | **Pending** | **Issued** | **Pending** | **Total** |
| Zileuton | 2 | 1 | 18 | 5 | 26 |
| HMGB1 | 10 | 13 | 22 | 34 | 79 |
| Alpha-7 | 4 | 8 | 10 | 21 | 43 |
| **Total** | 16 | 22 | 50 | 60 | 148 |

The U.S. patent covering the composition of matter of zileuton that Critical Therapeutics licensed from Abbott expires in December 2010. The patent for ZYFLO CR will expire in June 2012 and relates only to the controlled-release technology used to control the release of zileuton. The U.S. issued patents that Critical Therapeutics owns or exclusively licenses covering Critical Therapeutics product candidates other than zileuton expire on various dates between 2019 and 2021.

The patent position of pharmaceutical or biotechnology companies, including Critical Therapeutics, is generally uncertain and involves complex legal and factual considerations. Critical Therapeutics success depends, in part, on its ability to protect proprietary products, methods and technologies that it develops under the patent and other intellectual property laws of the United States and other countries, so that Critical Therapeutics can prevent others

from using its inventions and proprietary information. If any parties should successfully claim that Critical Therapeutics proprietary products, methods and technologies infringe upon their intellectual property rights, Critical Therapeutics might be forced to pay damages, and a court could require it to stop the infringing activity. Critical Therapeutics does not know if its pending patent applications will result in issued patents. Critical Therapeutics issued patents and those that may issue in the future, or those licensed to Critical Therapeutics, may be challenged, invalidated or circumvented, which could limit Critical Therapeutics ability to stop competitors from marketing related products or the length of term of patent protection that it may have for its products. In addition, the rights granted under any issued patents may not provide Critical Therapeutics with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, Critical Therapeutics competitors may independently develop similar

Table of Contents

technologies or duplicate any technology developed by it. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of Critical Therapeutics product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

***Trademarks, Trade Secrets and Other Proprietary Information***

Critical Therapeutics has registered the Critical Therapeutics name and logo in both the United States and the European Community. Critical Therapeutics has registered ZYFLO CR and CT2 in the United States. Critical Therapeutics has also filed trademark applications to register CRTX in the United States. In March 2004, Critical Therapeutics acquired the U.S. trademark for ZYFLO from Abbott.

In addition, Critical Therapeutics depends upon trade secrets, know-how and continuing technological advances to develop and maintain Critical Therapeutics competitive position. To maintain the confidentiality of trade secrets and proprietary information, it is Critical Therapeutics general practice to enter into confidentiality agreements with its employees, consultants, strategic partners, outside scientific collaborators and sponsored researchers and other advisors. These agreements are designed to protect Critical Therapeutics proprietary information. These agreements are designed to deter, but may not prevent, unauthorized disclosure of Critical Therapeutics trade secrets, and any such unauthorized disclosure would have a material adverse effect on Critical Therapeutics business, for which monetary damages from the party making such unauthorized disclosure may not be adequate to compensate Critical Therapeutics.

**Regulatory Matters**

The research, testing, manufacture and marketing of drug and biologic products are extensively regulated in the United States and abroad. In the United States, drugs and biologics are subject to rigorous regulation by the FDA. The federal Food, Drug, and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, packaging, labeling, advertising and promotion, sampling and distribution of pharmaceutical and biologic products. The failure to comply with the applicable regulatory requirements may subject Critical Therapeutics to a variety of administrative or judicially imposed sanctions, including the FDA s refusal to file new applications or to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

The steps ordinarily required before a new pharmaceutical or biologic product may be marketed in the United States include preclinical laboratory tests, animal tests and formulation studies, the submission to the FDA of an IND, which must become effective prior to commencement of human clinical testing, and adequate and well-controlled clinical trials to establish that the product is safe and effective for the indication for which FDA approval is sought. Satisfaction of FDA approval requirements typically takes several years and the actual time taken may vary substantially depending upon the complexity of the product, disease or clinical trials required. Government regulation may impose costly procedures on Critical Therapeutics activities, and may delay or prevent marketing of potential products for a considerable period of time or prevent such marketing entirely. Success in early stage clinical trials does not necessarily assure success in later stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in marketing or sales restrictions on the product or even complete withdrawal of the product from the market.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of compounds for testing must comply with federal regulations and requirements. The results of preclinical testing are submitted to the FDA as part of an IND during the IND stage of development and as part of the NDA.

**Table of Contents**

An IND must become effective prior to the commencement of clinical testing of a drug or biologic in humans. An IND will automatically become effective 30 days after receipt by the FDA if the FDA has not commented on or questioned the application during this 30-day waiting period. If the FDA has comments or questions, these may need to be resolved to the satisfaction of the FDA prior to commencement of clinical trials. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. The IND process can result in substantial delay and expense.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations and requirements, under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the safety and effectiveness criteria to be evaluated. Each protocol for an unapproved drug involving testing human subjects in the United States must be submitted to the FDA as part of the IND. The trial protocol and informed consent information for subjects in clinical trials must be submitted to institutional review boards for approval.

Clinical trials to support new drug or biologic product applications for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the product candidate into healthy human subjects or patients, the product is tested to assess metabolism, pharmacokinetics, safety, including side effects associated with increasing doses, and, at times, pharmacological actions. Phase II usually involves trials in a limited patient population, to determine dosage tolerance and optimum dosage, identify possible adverse effects and safety risks, and provide preliminary support for the efficacy of the product in the indication being studied.

If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to evaluate further clinical efficacy and to test further for safety within an expanded patient population, typically at geographically dispersed clinical trial sites. Phase I, Phase II or Phase III testing of any product candidates may not be completed successfully within any specified time period, if at all. Furthermore, the FDA, an institutional review board or Critical Therapeutics may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

After successful completion of the required clinical testing for a drug, generally an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all clinical and preclinical safety testing and a compilation of the data relating to the product s pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of NDAs are additionally subject to substantial application user fees, currently exceeding $1,100,000, the fee for submission of supplemental applications exceeds $580,000 and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently exceeding $65,000 per product and up to $392,000 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The review process is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA normally also will conduct a pre-approval inspection to ensure the manufacturing facility, methods and controls are adequate to preserve the drug s

identity, strength, quality, purity and stability, and are in compliance with regulations governing current good manufacturing practices. In addition, the FDA usually conducts audits of the clinical trials for new drug applications and efficacy supplements to ensure that the data submitted reflects the data generated by the clinical sites.

Table of Contents

If the FDA s evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue an approval letter, or, in some cases, a complete response letter followed by an approval letter. A complete response letter generally contains a statement that the application is not yet ready for approval and describes specific deficiencies and, if applicable, recommended actions an applicant might take to get the application ready for approval. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require post-approval trials and surveillance to monitor the drug s safety or efficacy and may impose other conditions, including labeling restrictions and restricted distribution, which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Supplemental applications must be filed for many post-approval changes, including changes in manufacturing facilities.

Some of Critical Therapeutics products may be regulated as biologics under the Public Health Service Act. Biologics must have a biologics license application, or BLA, approved prior to commercialization. Like NDAs, BLAs are subject to user fees. To obtain BLA approval, an applicant must provide preclinical and clinical evidence and other information to demonstrate that the biologic product is safe, pure and potent and that the facilities in which it is manufactured processed, packed or held meet standards, including good manufacturing practices and any additional standards in the license designed to ensure its continued safety, purity and potency. Biologics establishments are subject to preapproval inspections. The review process for BLAs is time consuming and uncertain, and BLA approval may be conditioned on post-approval testing and surveillance. Once granted, BLA approvals may be suspended or revoked under certain circumstances, such as if the product fails to conform to the standards established in the license.

Once the NDA or BLA is approved, a product will be subject to certain post-approval requirements, including requirements for adverse event reporting and submission of periodic reports. In addition, the FDA strictly regulates the promotional claims that may be made about prescription drug products and biologics. In particular, the FDA requires substantiation of any claims of superiority of one product over another, including that such claims be proven by adequate and well-controlled head-to-head clinical trials. To the extent that market acceptance of Critical Therapeutics products may depend on their superiority over existing therapies, any restriction on Critical Therapeutics ability to advertise or otherwise promote claims of superiority, or requirements to conduct additional expensive clinical trials to provide proof of such claims, could negatively affect the sales of Critical Therapeutics products or Critical Therapeutics costs.

Critical Therapeutics must also notify the FDA of any change in an approved product beyond variations already allowed in the approval. Certain changes to the product, its labeling or its manufacturing require prior FDA approval, including conduct of further clinical investigations to support the change. Major changes in manufacturing site require submission of an sNDA and approval by the FDA prior to distribution of the product using the change. Such supplements, referred to as Prior Approval Supplements, must contain information validating the effects of the change. An applicant may ask the FDA to expedite its review of such a supplement for public health reasons, such as a drug shortage. Approvals of labeling or manufacturing changes may be expensive and time-consuming and, if not approved, the product will not be allowed to be marketed as modified.

If the FDA s evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA and issue a complete response letter. The complete response letter outlines the deficiencies in the submission and often requires additional testing or information in order for the FDA to reconsider the application. Even after submitting this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of an NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

Once an NDA is approved, the product covered thereby becomes a listed drug that can, in turn, be cited by potential competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active pharmaceutical ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. There is

Table of Contents

no requirement, other than the requirement for bioequivalence testing, for an ANDA applicant to conduct or submit results of preclinical or clinical tests to prove the safety or efficacy of its drug product. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, are listed as such by the FDA, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active pharmaceutical ingredients but is approved in a new dosage, dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor. During such three-year exclusivity period, the FDA cannot grant effective approval of an ANDA to commercially distribute a generic version of the drug based on that listed drug. However, the FDA can approve generic equivalents of that listed drug based on other listed drugs, such as a generic that is the same in every way but its indication for use, and thus the value of such exclusivity may be undermined. Federal law also provides a period of five years following approval of a drug containing no previously approved active pharmaceutical ingredients. During such five-year exclusivity period, ANDAs for generic versions of those drugs cannot be submitted unless the submission accompanies a challenge to a listed patent, in which case the submission may be made four years following the original product approval. Additionally, in the event that the sponsor of the listed drug has properly informed the FDA of patents covering its listed drug, applicants submitting an ANDA referencing that drug are required to make one of four certifications, including certifying that it believes one or more listed patents are invalid or not infringed. If an applicant certifies invalidity or non-infringement, it is required to provide notice of its filing to the NDA sponsor and the patent holder. If the patent holder then initiates a suit for patent infringement against the ANDA sponsor within 45 days of receipt of the notice, the FDA cannot grant effective approval of the ANDA until either 30 months has passed or there has been a court decision holding that the patents in question are invalid or not infringed. If the NDA holder and patent owners do not begin an infringement action within 45 days, the ANDA applicant may bring a declaratory judgment action to determine patent issues prior to marketing. If the ANDA applicant certifies that it does not intend to market its generic product before some or all listed patents on the listed drug expire, then FDA cannot grant effective approval of the ANDA until those patents expire. If more than one applicant files a substantially complete ANDA on the same day for a previously unchallenged drug, each such first applicant will be entitled to share the 180-day exclusivity period, but there will only be one such period, beginning on the date of first marketing by any of the first applicants. The first ANDA submitting substantially complete applications certifying that listed patents for a particular product are invalid or not infringed may qualify for a period of 180 days after the first marketing of the generic product, during which subsequently submitted ANDAs cannot be granted effective approval.

Violation of any FDA requirements could result in enforcement actions, such as withdrawal of approval, product recalls, product seizures, injunctions, total or partial suspension of production or distribution, fines, consent decrees, civil penalties and criminal prosecutions, which could have a material adverse effect on Critical Therapeutics business.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the development, approval, manufacturing and marketing of drug products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect Critical Therapeutics business and its products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

***Foreign Regulation***

Approval of a product by comparable regulatory authorities may be necessary in foreign countries prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. The approval procedure varies among countries and can involve requirements for additional testing. The time required

may differ from that required for FDA approval. Although there are some procedures for unified filings for some European countries, such as the sponsorship of the country which first granted marketing approval, in general each country has its own procedures and requirements, many of which are time

Table of Contents

consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from foreign regulatory authorities after the relevant applications are filed.

Under European Union regulatory systems, marketing authorization applications may be submitted at a centralized, a decentralized or a national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all European Union member states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. Critical Therapeutics will choose the appropriate route of European regulatory filing to accomplish the most rapid regulatory approvals. However, Critical Therapeutics chosen regulatory strategy may not secure regulatory approvals on a timely basis or at all.

***Hazardous Materials***

Critical Therapeutics previous research and development processes involved the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. Critical Therapeutics is subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. Critical Therapeutics does not expect the cost of complying with these laws and regulations to be material.

**Competition**

The pharmaceutical and biotechnology industries in which Critical Therapeutics operate are characterized by rapidly advancing technologies and intense competition. Critical Therapeutics competitors include pharmaceutical companies, biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. All of these competitors currently engage in or may engage in the future in the development, manufacture and commercialization of new pharmaceuticals, some of which may compete with Critical Therapeutics present or future products and product candidates. Many of Critical Therapeutics competitors have greater development, financial, manufacturing, marketing and sales experience and resources than Critical Therapeutics does, and they may develop new products or technologies that will render Critical Therapeutics products or technologies obsolete or noncompetitive. Critical Therapeutics cannot assure you that Critical Therapeutics products will compete successfully with these newly emerging technologies. In some cases, competitors will have greater name recognition and may offer discounts as a competitive tactic.

A number of large pharmaceutical and biotechnology companies currently market and sell products to treat asthma that compete with ZYFLO CR. Many established therapies currently command large market shares in the asthma market, including Merck & Co., Inc. s Singulair®, GlaxoSmithKline plc s Advair® and inhaled corticosteroid products. In addition, Critical Therapeutics may face competition from pharmaceutical companies seeking to develop new drugs for the asthma market. For example, in June 2007, AstraZeneca commercially launched in the United States Symbicort®, a twice-daily asthma therapy combining budesonide, an inhaled corticosteroid, and formoterol, a long-acting beta2-agonist.

In the COPD market, zileuton, if Critical Therapeutics is able to develop it as a treatment for COPD, will face intense competition. COPD patients are currently treated primarily with a number of medications that are indicated for COPD, asthma or both COPD and asthma. The primary products used to treat COPD are anticholinergics, long-acting beta-agonists and combination long-acting beta-agonists and inhaled corticosteroids. These medications are delivered in various device formulations, including metered dose inhalers, dry powder inhalers and by nebulization. Lung reduction surgery is also an option for COPD patients.

Many therapies for COPD are already well established in the respiratory marketplace, including GlaxoSmithKline s Advair® and Serevent® and Spiriva®, a once-daily muscarinic antagonist from Boehringer Ingleheim GmbH and Pfizer. Other novel approaches are also in development.

Critical Therapeutics is also developing zileuton injection for use in the hospital emergency department for the treatment of acute asthma attacks. Critical Therapeutics may face intense competition from companies seeking

Table of Contents

to develop new drugs for use in severe acute asthma attacks. For example, Merck & Co., Inc. is conducting clinical trials of an intravenous formulation of its product Singulair®.

If Critical Therapeutics therapeutic programs directed toward the body s inflammatory response result in commercial products, such products will compete predominantly with therapies that have been approved for diseases such as rheumatoid arthritis, like Amgen, Inc. s Enbrel®, Johnson & Johnson s Remicade®, Bristol-Myers Squibb Company s Orencia®, Abbott Laboratories Humira® and Rituxan® marketed by Biogen Idec Inc. and Genentech, Inc., and diseases such as sepsis, like Eli Lilly and Company s Xigris®. While non-steroidal, anti-inflammatory drugs like ibuprofen are often used for the treatment of rheumatoid arthritis and offer efficacy in reducing pain and inflammation, Critical Therapeutics believes that Critical Therapeutics cytokine-based therapeutic programs will compete predominantly with the anti-TNF alpha therapies that have been approved for diseases such as rheumatoid arthritis, like Enbrel® and Remicade®. Xigris®, a product developed by Eli Lilly for sepsis, has received regulatory approval for severe sepsis patients. Other than a wide range of anti-infective drugs, Xigris is one of the only drugs approved by the FDA for the treatment of sepsis. Other companies are developing therapies directed towards cytokines. Critical Therapeutics does not know whether any or all of these products under development will ever reach the market and if they do, whether they will do so before or after Critical Therapeutics products are approved.

Critical Therapeutics competitors products may be safer, more effective, more convenient or more effectively marketed and sold, than any of Critical Therapeutics products. Many of Critical Therapeutics competitors have:

- significantly greater financial, technical and human resources than Critical Therapeutics has and may be better equipped to discover, develop, manufacture and commercialize products;
- more extensive experience than Critical Therapeutics has in conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;
- competing products that have already received regulatory approval or are in late-stage development; and
- collaborative arrangements in Critical Therapeutics target markets with leading companies and research institutions.

Critical Therapeutics will face competition based on the safety and effectiveness of its products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Critical Therapeutics competitors may develop or commercialize more effective, safer or more affordable products, or obtain more effective patent protection, than Critical Therapeutics is able to. Accordingly, Critical Therapeutics competitors may commercialize products more rapidly or effectively than Critical Therapeutics is able to, which would adversely affect Critical Therapeutics competitive position, the likelihood that its product candidates will achieve initial market acceptance and its ability to generate meaningful revenues from its product candidates. Even if Critical Therapeutics product candidates achieve initial market acceptance, competitive products may render its products obsolete or noncompetitive. If Critical Therapeutics product candidates are rendered obsolete, it may not be able to recover the expenses of developing and commercializing those product candidates.

**Properties**

Critical Therapeutics subleases approximately 11,298 square feet of office space in Lexington, Massachusetts. The sublease expires on February 28, 2009, and Critical Therapeutics has an option to extend the term of the sublease for an additional six months by providing written notice on or prior to October 31, 2008. Critical Therapeutics believes its facilities are sufficient to meet its needs for the foreseeable future.

188

Table of Contents

**Employees**

As of September 15, 2008, Critical Therapeutics had 42 full-time employees, 29 of whom were engaged in marketing and sales, two of whom were engaged in development and regulatory affairs, and 11 of whom were engaged in management, administration and finance. None of Critical Therapeutics employees are represented by a labor union or covered by a collective bargaining agreement. Critical Therapeutics has not experienced any work stoppages. Critical Therapeutics believes that relations with its employees are good.

**Legal Proceedings**

On September 17, 2008, a purported shareholder class action lawsuit was filed by a single plaintiff against Critical Therapeutics and each of its directors in the Court of Chancery of The State of Delaware. The action is captioned *Jeffrey Benison IRA v. Critical Therapeutics, Inc., Trevor Phillips, Richard W. Dugan, Christopher Mirabelli, and Jean George* (Case No. 4039, Court of Chancery, State of Delaware). The plaintiff, which claims to be a stockholder of Critical Therapeutics, brought the lawsuit on its own behalf, and is seeking certification of the lawsuit as a class action on behalf of all stockholders of Critical Therapeutics, except the defendants and their affiliates. The complaint alleges, among other things, that the defendants breached fiduciary duties of loyalty and good faith, including a fiduciary duty of candor, by failing to provide Critical Therapeutics stockholders with a proxy statement/prospectus adequate to enable them to cast an informed vote on the proposed merger, and by possibly failing to maximize stockholder value by entering into an agreement that effectively discourages competing offers. The complaint seeks, among other things, an order (i) enjoining the defendants from proceeding with or implementing the proposed merger on the terms and under the circumstances as they presently exist, (ii) invalidating the provisions of the proposed merger that purportedly improperly limit the effective exercise of the defendants continuing fiduciary duties; (iii) ordering defendants to explore alternatives and to negotiate in good faith with all *bona fide* interested parties; (iv) in the event the proposed merger is consummated, rescinding it and setting it aside or awarding rescissory damages; (v) awarding compensatory damages against defendants, jointly and severally; and (vi) awarding the plaintiff and the purported class their costs and fees.

Critical Therapeutics intends to defend against this lawsuit vigorously.

**Access to SEC Filings**

Critical Therapeutics files reports, proxy statements and other information with the SEC as required by the Exchange Act. You can find, copy and inspect information Critical Therapeutics files at the SEC s public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can call the SEC at 1-800-SEC-0330 for further information about the public reference room. You can review Critical Therapeutics electronically filed reports, proxy and information statements on the SEC s web site at http:// www.sec.gov or on Critical Therapeutics web site at http://www.crtx.com.

Table of Contents

## CORNERSTONE S BUSINESS

### Overview

Cornerstone is a specialty pharmaceutical company focused on acquiring, developing and commercializing prescription products for the respiratory market. Cornerstone currently promotes four marketed products in the United States to respiratory-focused physicians and key retail pharmacies with its 50 person specialty sales force. Cornerstone s commercial strategy is to acquire non-promoted or underperforming branded pharmaceutical products and then maximize their potential value by promoting the products using its sales and marketing capabilities and applying various product life cycle management techniques. Cornerstone s product development pipeline consists of three line extensions of one of its currently marketed products and a portfolio of additional product candidates based on marketed drug compounds. Cornerstone also generates revenue from the sale of seven marketed product lines that include products that it does not promote. Two of these seven product lines include products that are promoted by third parties, and six of these product lines include products that are not promoted by Cornerstone or any third party. Four of these six product lines include generic products that Cornerstone markets through Aristos Pharmaceuticals, Inc., or Aristos, one of its wholly owned subsidiaries. Cornerstone recognized net revenues of $23.5 million in the six months ended June 30, 2008, $28.1 million in 2007, $22.1 million in 2006 and $17.5 million in 2005.

Cornerstone actively promotes the following four respiratory products because it believes they are most responsive to promotional efforts: SPECTRACEF and three ALLERX Dose Pack products. SPECTRACEF is an oral antibiotic indicated for the treatment of mild to moderate infections caused by pathogens associated with particular respiratory tract infections. Cornerstone s three ALLERX Dose Pack products are oral tablets indicated for the temporary relief of symptoms associated with allergic rhinitis. These four promoted products generated aggregate net sales of $14.3 million in the six months ended June 30, 2008 and $20.4 million in 2007. The products that Cornerstone does not promote generated additional aggregate net revenues of $9.2 million in the six months ended June 30, 2008 and $7.0 million in 2007.

As of September 15, 2008, Cornerstone s only products that are subject to approved NDAs or ANDAs are SPECTRACEF, BALACET 325, APAP 325 and APAP 500. Cornerstone markets its remaining products without an FDA-approved marketing application because Cornerstone considers them to be identical, related or similar to products that have existed in the market without an FDA-approved marketing application, and which were thought not to require pre-market review and approval, or which were approved only on the basis of safety, at the time they entered the marketplace, subject to FDA enforcement policies established in connection with the FDA s DESI program. For a more complete discussion regarding FDA drug approval requirements, please see the section entitled Risks Related to Cornerstone Some of Cornerstone s specialty pharmaceutical products are now being marketed without approved NDAs or ANDAs beginning on page 70 of this proxy statement/prospectus and the section entitled Cornerstone s Business Regulatory Matters beginning on page 222 of this proxy statement/prospectus.

Cornerstone s product development pipeline includes the following three SPECTRACEF line extensions: a 400 mg dose tablet, a once daily dosage tablet and an oral suspension for the pediatric market. Cornerstone s product development pipeline also includes the following three additional product candidates: a methscopolamine and antihistamine combination product candidate for the treatment of symptoms of allergic rhinitis and two extended-release antitussive, or cough suppressant, combination product candidates. Cornerstone believes that it can substantially mitigate the risks and uncertainties and reduce the time and costs typically associated with new drug development by utilizing Section 505(b)(2) of the FDCA, or by filing sNDAs or ANDAs with the FDA for approval of most of its product candidates. These development pathways provide the potential for expedited development of new formulations of existing compounds because they allow Cornerstone to rely in part on the findings of safety and

efficacy of products already approved by the FDA in support of Cornerstone s applications for approval of new or improved formulations. In situations in which it deems appropriate, Cornerstone may choose to develop new formulations of existing compounds that require Cornerstone to conduct new clinical trials to obtain FDA marketing approval. If clinical trials are required in connection with approval of a product candidate, the new formulation may qualify for a three-year period of marketing exclusivity in the United States under the Hatch-Waxman Act. Cornerstone received

Table of Contents

approval of its sNDA for its SPECTRACEF 400 mg line extension in July 2008 and expects to submit applications for approval to the FDA for each of its other current product candidates by the end of 2010.

**Strategy**

Cornerstone s goal is to become a leading specialty pharmaceutical company that acquires, develops and commercializes significant products for the respiratory market. Key elements of Cornerstone s strategy to achieve this goal include the following:

***Grow Product Revenue through a Specialty Sales Force Focused on the Respiratory Market.***

Cornerstone intends to increase revenue from product sales by using its commercial resources, including its specialty sales force, to target respiratory specialists and primary care physicians who are high-prescribers of respiratory products. By concentrating its resources on the respiratory market, Cornerstone believes that it can increase its profile among prescribers, maximize the sales of its current products and enhance its ability to acquire additional products and product candidates. Cornerstone expects that revenue from sales of its products will be a significant source of funds for product acquisition, development and commercialization.

***Acquire Rights to Under-Promoted, Patent-Protected, Branded Respiratory Pharmaceutical Products.***

Cornerstone continues to seek to expand its product portfolio through the acquisition of rights to FDA-approved respiratory pharmaceutical products with well-established safety and efficacy profiles and projected annual sales potential that large pharmaceutical companies may view as insufficient to justify the time required and the investment necessary to promote with a large sales force. Cornerstone believes that its experience and relationships in the specialty pharmaceutical industry will allow it to identify and acquire products that are under-promoted and would benefit from a focused sales and marketing effort using Cornerstone s commercial resources. Since inception, Cornerstone has acquired or licensed rights to the SPECTRACEF, ALLERX, HYOMAX, DECONSAL, propoxyphene/acetaminophen, Extendryl and Humibid product lines through its business development network and capabilities. As of September 15, 2008, Cornerstone generated revenues from each of these product lines, other than the Humibid product line, the rights to which it transferred to Adams in February 2005.

***Implement Life Cycle Management Strategies.***

Cornerstone expects to continue its efforts to implement life cycle management strategies to maximize the potential value of its currently marketed products, newly acquired products and product candidates that are currently in development. These strategies involve securing FDA approval for additional indications for existing products, developing line extensions in the form of new dosages and formulations of products that offer improvements in patient convenience, compliance or safety and introducing generic formulations of certain of Cornerstone s products through its Aristos subsidiary. In the case of SPECTRACEF, for example, Cornerstone received approval from the FDA in July 2008 for an sNDA for a 400 mg tablet for twice daily dosing of SPECTRACEF that Cornerstone believes would improve patient convenience as compared to the current dosing of two 200 mg tablets twice daily. A key aspect of this strategy involves the use of proprietary drug delivery and formulation technologies, such that, if approved, the new products may have patent protection or market exclusivity while being commercialized.

***Pursue Strategic Relationships on a Selective Basis for Product Development or Commercialization.***

Cornerstone has entered into and may seek to enter into additional strategic relationships with third parties in order to facilitate the development and commercialization of its products and product candidates. In particular, Cornerstone expects to enter into arrangements that provide it with access to drug delivery and formulation technologies if

Cornerstone determines that it is cost effective to do so given the anticipated return on its investment. In addition, Cornerstone has entered into and may seek to enter into additional co-promotion arrangements to enhance its promotional efforts and, therefore, sales of its products. By entering into agreements with pharmaceutical companies that have experienced sales forces with strong management

Table of Contents

support, Cornerstone can reach health care providers in areas where it has limited or no sales force representation.

**Marketed Products**

Cornerstone currently actively promotes four of its marketed products. The following table sets forth additional information regarding Cornerstone s currently marketed products that it actively promotes.

| Promoted Product | Cornerstone Launch Date | Active Pharmaceutical Ingredient(s) | Primary Indication | Six Months Ended June 30, 2008 Net Sales (In thousands) | 2007 Net Sales |
|---|---|---|---|---|---|
| SPECTRACEF | November 2006 | Cefditoren | Treatment of mild to moderate infections that are caused by susceptible strains of microorganisms in community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis, pharyngitis and tonsillitis and uncomplicated skin and skin-structure infections | $1,795 | $6,886 |
| ALLERX Dose Pack | February 2005(1) | AM dose: Pseudoephedrine and methscopolamine<br><br>PM dose:<br><br>Phenylephrine, chlorpheniramine and methscopolamine | Temporary relief of symptoms associated with allergic rhinitis | 6,015 | 11,103 |
| ALLERX Dose Pack DF (decongestant-free) | August 2006 | AM dose:<br><br>Chlorpheniramine and methscopolamine<br><br>PM dose:<br><br>Chlorpheniramine and methscopolamine | Temporary relief of symptoms associated with allergic rhinitis | 2,554 | 967 |

| | | | | | |
|---|---|---|---|---|---|
| ALLERX Dose Pack PE | September 2006 | AM dose:<br><br>Phenylephrine and methscopolamine<br><br>PM dose:<br><br>Phenylephrine, chlorpheniramine and methscopolamine | Temporary relief of symptoms associated with allergic rhinitis | 3,935 | 1,439 |

(1) ALLERX Dose Pack was reformulated in February 2008 as ALLERX 10 Dose Pack/ALLERX 30 Dose Pack.

Cornerstone s marketed products that it does not promote generated additional aggregate net revenues of $9.2 million in the six months ended June 30, 2008 and $7.0 million in 2007.

***SPECTRACEF***

*Overview*

SPECTRACEF, an antibiotic administered orally in tablet form, is a third generation cephalosporin with the API cefditoren pivoxil, a semi-synthetic cephalosporin. SPECTRACEF is indicated for the treatment of mild to

moderate infections in adults and adolescents 12 years of age or older that are caused by pathogens associated with particular respiratory tract infections, including community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis, pharyngitis and tonsillitis and uncomplicated skin and skin-structure infections. Cornerstone s net sales of SPECTRACEF were $6.9 million in 2007 and $1.8 million in the six months ended June 30, 2008.

*Market Opportunity and Other Treatment Options*

According to a 2006 Datamonitor report, each year an average of approximately 88 million patients in the United States are diagnosed with respiratory tract infections, including approximately 25 million with acute exacerbations of chronic bronchitis, 22 million with acute bacterial sinusitis and 19 million with community-acquired pneumonia. According to this Datamonitor report, physicians typically select respiratory tract infection treatments empirically without prior identification of the specific pathogen causing the infection, although antibiotic therapy is the most common form of treatment regardless of whether the bacterial pathogen can be identified. If the specific pathogen has not been identified, health care providers sometimes choose which class of antibiotic to prescribe based on the most likely pathogen causing the infection based on the patient s symptoms.

The U.S. oral antibiotic market is fairly fragmented, with approximately 40 branded products and more than 50 generic products. Pharmacists typically fill prescriptions for antibiotics with generic products when available. According to Wolters Kluwer Health, a third-party provider of prescription data, in 2007, the U.S. oral solid antibiotic market generated approximately 220 million prescriptions, including approximately 44 million for macrolides, such as generic formulations of Pfizer Inc. s Zithromax® (azithromycin) and Abbott Laboratories, Inc. s Biaxin® (clarithromycin), approximately 38 million for quinolones, such as Ortho-McNeil-Janssen Pharmaceuticals, Inc. s Levaquin® (levofloxacin) and generic formulations of Bayer AG s Cipro® (ciprofloxacin), and approximately 8 million for second and third generation cephalosporins, such as SPECTRACEF and Shionogi USA, Inc. s Cedax® (ceftibuten) and generic formulations of Abbott Laboratories, Inc. s Omnicef® (cefdinir), Pharmacia and Upjohn Company, Inc. s Vantin® (cefpodoxime), GlaxoSmithKline plc s Ceftin® (cefuroxime), Bristol-Myers Squibb Company s Cefzil® (cefprozil) and Eli Lilly & Company s Ceclor® (cefaclor). The only branded oral solid cephalosporin products currently without generic competition in the United States are SPECTRACEF, Cedax and Lupin Pharmaceuticals Suprax® (cefixime), which was recently re-introduced.

Macrolides generally are broad spectrum, have a low incidence of side effects and have convenient dosing regimens. However, macrolides can be associated with severe allergic reactions and interactions with many other commonly prescribed drugs that can affect potency. In addition, *Streptococcus pneumoniae,* a bacterium causing lung infections, displays a high incidence of resistance to macrolide antibiotics. Quinolones generally are considered safe and efficacious overall and have convenient dosing regimens. Quinolones, however, have multiple interactions with commonly prescribed drugs, cannot be used in children and have been associated with tendon rupture and photosensitivity adverse reactions. Cephalosporins, including SPECTRACEF, generally cause few side effects. Common side effects are gastrointestinal in nature and are mild and transient.

Cephalosporins are classified in the United States based on their spectrum of activity against different types of bacteria. Bacteria are broadly classified into two categories based on the composition of their cell wall structure: gram-positive or gram-negative. In general, cephalosporins developed more recently as follow-on products to the first generation of cephalosporins approved for marketing, commonly referred to as second and third generation cephalosporins, have greater activity against gram-negative bacteria than earlier generations, but decreasing activity against gram-positive bacteria. First generation cephalosporins have good activity against gram-positive bacteria, including *Staphylococcus aureus*, a bacterium associated with skin infections, and *Streptococcus pyogenes*, a bacterium associated with pharyngitis and tonsillitis. Second generation cephalosporins have greater activity against gram-negative bacteria, such as *Haemophilus influenzae*, but also retain some activity against gram-positive bacteria, including *Staphylococcus aureus* and *Streptococcus pyogenes*. Second generation cephalosporins also have some

activity against bacteria, such as *Haemophilus influenzae* and *Moraxella catarrhalis,* that produce ß-lactamase, an enzyme that is able to destroy some antibiotics before they can exert their effects on the bacteria. Third generation cephalosporins have even

greater activity against a broad spectrum of gram-negative bacteria, such as *Haemophilus influenzae* and *Moraxella catarrhalis*, including strains of bacteria that produce ß-lactamase, but often have decreased activity against gram-positive bacteria.

Cornerstone believes that SPECTRACEF currently is the only branded second or third generation oral solid cephalosporin product being actively promoted to health care providers in the adult respiratory market, although Suprax is being promoted within the pediatric market by Lupin Pharmaceuticals specialty sales force, and Suprax is being promoted by Ascend Therapeutics, Inc. s specialty sales force to obstetricians and gynecologists pursuant to a co-promotion agreement with Lupin Pharmaceuticals.

*Benefits of SPECTRACEF*

SPECTRACEF is effective against several common respiratory pathogens, including the three most prevalent pathogens in respiratory tract infections as reported in the 2006 Datamonitor report, *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*. In two previously conducted and published clinical trials, cefditoren, present in SPECTRACEF as cefditoren pivoxil, demonstrated superior potency as compared to cefdinir, cefuroxime and cefprozil against community-acquired *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*.

*Proprietary Rights*

Cornerstone has an exclusive license from Meiji to market SPECTRACEF and related product candidates in the United States under both an issued U.S. patent with claims to the composition of matter of the API in SPECTRACEF, cefditoren pivoxil, and an issued U.S. patent with claims to the formulation of products like SPECTRACEF that contain a mixture of cefditoren pivoxil with a water soluble casein salt. The composition of matter patent expires in April 2009 and the formulation patent expires in 2016. Cornerstone has also licensed from Meiji the U.S. trademark rights to SPECTRACEF.

***ALLERX***

*Overview*

Cornerstone s ALLERX Dose Pack products are oral tablets indicated for the temporary relief of symptoms associated with allergic rhinitis. Each ALLERX Dose Pack product contains the antihistamine chlorpheniramine, a choice of decongestant, including an option without a decongestant, and methscopolamine, an anticholinergic, or drying agent, which provides additional symptomatic relief by drying up the mucosal secretions associated with allergic rhinitis. Cornerstone s net sales of ALLERX Dose Pack products were $13.5 million in 2007 and $6.0 million in the six months ended June 30, 2008.

*Market Opportunity and Other Treatment Options*

The American Academy of Allergy, Asthma & Immunology, or AAAAI, defines rhinitis as an inflammation of the mucous membranes of the nose with symptoms of sneezing, itching, nasal discharge and congestion. Rhinitis can be allergic, nonallergic or both. Seasonal allergic rhinitis is caused by substances that trigger allergies, called allergens, and is sometimes referred to as hay fever.

According to the Centers for Disease Control and Prevention, or CDC, allergic rhinitis is believed to be responsible for approximately 14.1 million physician visits annually. According to a January 2006 Allergies in America survey, approximately 69% of patients with allergic rhinitis had taken medication for their nasal allergies in the prior four

weeks, including 45% who took prescription medication. The survey also reported that 40% of patients surveyed indicated that nasal allergies had a lot or a moderate amount of impact on their daily life, compared with only 33% of patients who indicated that nasal allergies had little or no impact on their daily life.

According to the Allergies in America survey, allergies contribute to an average productivity loss of 25% among workers who suffer from allergies on days when their allergies are at their worst, and allergies resulted in missed workdays for 30% of sufferers in the past year.

Table of Contents

The cough, cold and allergy market is very fragmented with hundreds of brands and even more generics. This market includes prescription and over-the-counter antihistamine and antihistamine combination products. First generation antihistamines are widely available and have been used for more than 50 years. They are associated with the side effect of sedation, which can interfere with the patient s quality of life. Some first generation antihistamines, such as chlorpheniramine, also exhibit some anticholinergic effects. Second generation antihistamines were introduced because they are less sedating than first generation antihistamines, but some second generation antihistamines have been linked to cardiac risks. Third generation antihistamines, which are metabolites of second generation antihistamines, are less sedating than first generation antihistamines and have not been associated with cardiac risks. Unlike first generation antihistamines, neither second generation nor third generation antihistamines exhibit anticholinergic effects. In the January 2006 Allergies in America survey, 62% of allergy sufferers reported a runny nose and 61% of allergy sufferers reported post-nasal drip as usually extremely or moderately bothersome during allergy attacks.

First generation prescription antihistamine and antihistamine combination products include Capellon Pharmaceuticals, Ltd. s Rescon-MX® (chlorpheniramine, methscopolamine and phenylephrine), Poly Pharmaceuticals, Inc. s Poly Hist Forte® (chlorpheniramine, phenylephrine and pyrilamine) and Laser Pharmaceuticals, LLC s Dallergy® (phenylephrine, chlorpheniramine and methscopolamine). Over-the-counter products include well known brands such as McNeil-PPC, Inc. s Zyrtec® (cetirizine hydrochloride) and Schering-Plough Corporation s Claritin® (loratadine), McNeil-PPC, Inc. s Benadryl® (diphenhydramine) and Schering-Plough Corporation s Chlor-Trimeton® (chlorpheniramine). According to Wolters Kluwer Health, in 2007, oral solid first generation antihistamine and antihistamine combination products generated approximately 6.6 million prescriptions. The ALLERX Dose Pack family of products is the market leader among branded first generation antihistamine and antihistamine combination products, generating approximately 284,000 prescriptions in 2007.

In addition to pharmacotherapy, such as antihistamines and decongestants, there are two other principal treatment options for allergic rhinitis: allergen avoidance and immunotherapy.

According to AAAAI, allergen avoidance is the best treatment, but it is often difficult to avoid the allergy trigger. Immunotherapy, commonly referred to as allergy shots, is a treatment that stimulates the immune system to fight allergies through an immunization procedure beginning with injections of purified extract substances that are causing the allergic reactions. Immunotherapy can be very effective and can decrease the sensitivity of the patient to allergens, but it is time consuming for the patient and can be costly.

Antihistamine therapy typically does not help with congestion, and first generation antihistamines are associated with the side effect of sedation. Decongestants aid with the symptom of congestion but do not help block histamines and are commonly associated with the side effects of insomnia, anxiety and increased heart rate.

*Benefits and Description of ALLERX Dose Packs*

ALLERX Dose Packs use a patented dosing regimen and are designed so that side effects, such as insomnia with decongestants and drowsiness with first generation antihistamines, to the extent they are experienced, are most likely to occur at times that these side effects do not inconvenience the patient.

Cornerstone currently markets the following ALLERX Dose Pack products.

*ALLERX 10 Dose Pack/ALLERX 30 Dose Pack*

These ALLERX Dose Pack products are available in ten-day and 30-day regimens and consist of a morning, or AM, dose and an evening, or PM, dose. The AM dose contains 120 mg of the decongestant pseudophedrine, which also

helps patients stay alert during the day, and 2.5 mg of the drying agent methscopolamine. The PM dose contains 8 mg of the antihistamine chlorpheniramine, which helps patients sleep better at night by relieving their symptoms and making them drowsy, 10 mg of the decongestant phenylephrine and 2.5 mg of methscopolamine.

Table of Contents

*ALLERX Dose Pack DF/ALLERX Dose Pack DF 30*

ALLERX Dose Pack DF is a decongestant-free dosing regimen suitable for patients who cannot tolerate a decongestant but need the antihistamine and drying agent to relieve their symptoms. ALLERX Dose Pack DF is available in ten-day and 30-day regimens and consists of an AM dose and a PM dose. The AM dose contains 4 mg of the antihistamine chlorpheniramine and 2.5 mg of the drying agent methscopolamine. The PM dose contains 8 mg of chlorpheniramine and 2.5 mg of methscopolamine.

*ALLERX Dose Pack PE/ALLERX Dose Pack PE 30*

ALLERX Dose Pack PE substitutes the decongestant phenylephrine for pseudoephedrine in the AM dose. ALLERX Dose Pack PE may be preferred by physicians who prefer phenylephrine or who are concerned that products containing pseudoephedrine have been widely reported by law enforcement personnel as having been used as component ingredients for the illegal manufacture of methamphetamines. It is also suitable for patients who cannot tolerate pseudoephedrine. ALLERX Dose Pack PE is available in ten-day and 30-day regimens and consists of an AM dose and a PM dose. The AM dose contains 40 mg of phenylephrine and 2.5mg of the drying agent methscopolamine. The PM dose contains 10 mg of phenylephrine, 8 mg of the antihistamine chlorpheniramine and 2.5mg of methscopolamine.

*Proprietary Rights*

Cornerstone has an exclusive license from Pharmaceutical Innovations to market ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30 within the United States under an issued U.S. patent with claims to a prepackaged, therapeutic dosing regimen that includes a less sedating first dose containing a nasal decongestant, a second dose containing an antihistamine and an attenuated dosage of nasal decongestant, indicia for distinguishing between the first and second doses, administration instructions that teach the coordinated use of the first and second doses and a pharmaceutical dispensing container containing the first and second doses and incorporating the indicia and coordinating instructions. This patent expires in 2021. On June 13, 2008, the U.S. Patent and Trademark Office received a request from Vision Pharma, LLC, or Vision, to re-examine this patent. These re-examination proceedings are more fully discussed in the section entitled Cornerstone s Business Legal Proceedings beginning on page 232 of this proxy statement/prospectus.

In addition, Cornerstone has applied for a U.S. patent that, if issued, would include claims to ALLERX Dose Pack DF s and ALLERX Dose Pack DF 30 s AM and PM dosing regimen and method of treating a rhinitic condition using an antihistamine and an anticholinergic in both doses. This patent application has been published and is currently pending. If issued, this patent would expire in 2026.

**Other Products**

***HYOMAX***

*Overview*

The HYOMAX line of products consists of generic formulations of four antispasmodic medications containing the API hyoscyamine sulfate, an anticholinergic, which may be prescribed for functional intestinal disorders to reduce symptoms such as those seen in mild dysenteries and diverticulitis. The HYOMAX line of products can also be used to control gastric secretion, visceral spasm and hypermotility in cystitis, pylorospasm and associated abdominal cramps. Along with appropriate analgesics, HYOMAX products may be prescribed for symptomatic relief of biliary and renal colic and as a drying agent in the relief of symptoms of acute rhinitis. HYOMAX products may also be used

as adjunctive therapy in the treatment of peptic ulcer and irritable bowel syndrome, acute enterocolitis and other functional gastrointestinal disorders. Cornerstone launched the first HYOMAX product, HYOMAX SL 0.125 mg tablets, in May 2008, followed by HYOMAX SR 0.375 mg tablets and HYOMAX FT 0.125 mg chewable melt tablets in June 2008 and HYOMAX DT 0.125 mg immediate release/0.25 mg sustained release biphasic tablets in July 2008. Cornerstone markets the HYOMAX line of products through its Aristos subsidiary. Cornerstone formed Aristos to launch authorized generic

versions of Cornerstone s products that become subject to generic competition and to acquire or in-license generic versions of products with little or no generic competition, such as the HYOMAX line of products, that Cornerstone s management believes offer attractive returns on investment, regardless of whether such products are used to treat respiratory ailments.

*Market Opportunity and Other Treatment Options*

Antispasmodics are often a first-line treatment for patients with irritable bowel syndrome, or IBS, because they offer a safe, cost-effective method of relieving abdominal pain and diarrhea by preventing or slowing contractions in the bowel.

According to the American Academy of Family Physicians, 10% to 15% of the U.S. population is affected by IBS to some degree. According to the American Physical Therapy Association, more than 17 million Americans have urinary incontinence, although only 15% seek treatment. Patients with urinary incontinence may find that antispasmodics relax the bladder muscle and relieve spasms.

The U.S. antispasmodic market is fairly fragmented with approximately 30 branded products and 20 generic products. According to Wolters Kluwer Health, in 2007, in the United States the antispasmodic market generated approximately 25 million prescriptions, including approximately 16 million for urinary incontinence antispasmodics, such as Pfizer Inc. s Detrol® LA (tolterodine tartrate), Astellas Pharmaceuticals, Inc. and GlaxoSmithKline s VESIcare® (solifenacin) and the generic formulations of Ortho-McNeil Pharmaceutical, Inc. s Ditropan® and Ditropan® XL (oxybutynin), approximately 3.6 million for synthetic gastrointestinal antispasmodics, such as the generic formulations of Axcan Pharma, Inc. s Bentyl® (dicyclomine) and Kenwood Therapeutics Pamine® (methscopolamine bromide) and approximately 4.4 million for belladonna and derivatives gastrointestinal antispasmodics, such as the HYOMAX products, and generic formulations of Alaven Pharmaceutical LLC s Levsin® (hyoscyamine sulfate) and Levbid® (hyoscyamine sulfate) products and of PBM Pharmaceuticals Donnatal® (belladonna alkaloids/phenobarbital). All brands in the belladonna and derivatives gastrointestinal antispasmodics market have a generic formulation. Some newer products for IBS, such as Prometheus Laboratories, Inc. s Lotronex® (alosetron) and Novartis Pharmaceuticals Corporation s, or Novartis, Zelnorm® (tegaserod), have been subject to FDA risk assessment. Lotronex was introduced and voluntarily withdrawn from the market in 2000 due to concerns of the severity and number of adverse results from the use of the product, but was reintroduced to the market in 2002 after Novartis agreed with the FDA to institute a Patient-Physician Agreement program. Zelnorm was introduced to the market in 2002 and similarly voluntarily withdrawn from the market in 2007 after findings of an increased risk of serious cardiovascular adverse events associated with the use of the drug.

*Benefits of HYOMAX*

Once absorbed, hyoscyamine sulfate, the API in the HYOMAX products, disappears rapidly from the blood and is distributed throughout the entire body. The majority of hyoscyamine sulfate is excreted in the urine unchanged within the first 12 hours and only traces of hyoscyamine sulfate are found in the breast milk of nursing mothers. The HYOMAX line of products offers patients a cost-effective treatment option for a variety of gastrointestinal problems, such as IBS and urinary incontinence and may be preferred by physicians concerned about the potential serious side effects associated with newer products such as Zelnorm.

*Proprietary Rights*

Cornerstone has an exclusive license from Sovereign Pharmaceuticals, Ltd., or Sovereign, to market and distribute three hyoscyamine sulfate products in the United States through April 2011. Cornerstone is marketing and distributing HYOMAX DT tablets in the United States pursuant to a verbal agreement between Cornerstone and Capellon

Pharmaceuticals, Ltd., or Capellon, a wholly owned subsidiary of Sovereign, which the parties anticipate will be superseded by a written license agreement that is currently being negotiated and finalized between Cornerstone and Capellon. Cornerstone filed for the trademark to HYOMAX in May 2008 for use in connection with marketing this product line.

Table of Contents

***ALLERX***

*ALLERX-D*

ALLERX-D contains 120 mg of the decongestant pseudoephedrine and 2.5 mg of the drying agent methscopolamine. Packaged in bottles, ALLERX-D provides patients symptomatic relief of the symptoms of allergic rhinitis without an antihistamine.

*ALLERX Suspension*

ALLERX Suspension is an oral, liquid decongestant and antihistamine combination that is indicated for patients six years of age or older for symptomatic relief of the nasal inflammation and nasal congestion associated with the common cold, sinusitis and other upper respiratory tract conditions. Each 5 ml dose contains 7.5 mg of the decongestant phenylephrine tannate and 3 mg of the antihistamine chlorpheniramine tannate.

***RESPIVENT***

Cornerstone currently markets two RESPIVENT products, RESPIVENT-D and RESPIVENT DF Dose Pack. RESPIVENT-D is a generic formulation of ALLERX-D. RESPIVENT DF Dose Pack is a generic formulation of ALLERX Dose Pack DF, which, like ALLERX Dose Pack DF, is available in ten-day and 30-day regimens.

***Propoxyphene/Acetaminophen Products***

Cornerstone s propoxyphene/acetaminophen product line includes BALACET 325, APAP 325 and APAP 500. Cornerstone acquired the rights to each of these products from Vintage.

*BALACET 325*

BALACET 325 is indicated for the relief of mild to moderate pain, either when pain is present alone or when it is accompanied by a fever. BALACET 325 contains 100 mg of propoxyphene napsylate and 325 mg of acetaminophen. Cornerstone licensed rights to the formulation of BALACET 325 from Vintage in 2004. Cornerstone s net sales of BALACET 325 were $4.4 million in 2007. BALACET 325 is currently promoted by Atley Pharmaceuticals under a co-promotion agreement with Cornerstone.

*APAP 325*

APAP 325 is a generic formulation of BALACET 325 and indicated for the relief of mild to moderate pain. Each tablet contains 100 mg of propoxyphene napsylate and 325 mg of acetaminophen. APAP 325, along with any other generic formulation of BALACET 325, is currently promoted by Atley Pharmaceuticals under a co-promotion agreement with Cornerstone.

*APAP 500*

APAP 500 is a generic formulation of Xanodyne Pharmaceuticals, Inc. s Darvocet a500 and indicated for the relief of mild to moderate pain. Each tablet contains 100 mg of propoxyphene napsylate and 500 mg of acetaminophen.

Table of Contents

**Product Development Pipeline**

Cornerstone s product development pipeline consists of three SPECTRACEF line extensions and a portfolio of additional product candidates based on marketed drug compounds. The following table sets forth additional information regarding Cornerstone s product candidates.

| Product Candidate | Regulatory Status | Therapeutic Class | Method of Administration | Primary Indication(s) |
|---|---|---|---|---|
| Spectracef Line Extensions | | | | |
| SPECTRACEF 400 mg | sNDA approved in July 2008 | Antibiotic | Oral tablet Twice-daily dosing | Acute bacterial exacerbation of chronic bronchitis; community-acquired pneumonia |
| SPECTRACEF Once Daily | NDA submission targeted in 2010 | Antibiotic | Oral tablet Once-daily Dosing | Acute bacterial exacerbations of chronic bronchitis with COPD |
| SPECTRACEF Suspension | NDA submission for pharyngitis and tonsillitis targeted in 2009; sNDA submission for acute otitis media targeted in 2010 | Antibiotic | Oral suspension | Pharyngitis and tonsillitis; acute otitis media |
| Other Product Candidates | | | | |
| CBP 058 | NDA submission targeted in 2010 | Antihistamine and anticholinergic combination | Oral tablet | Temporary relief of symptoms associated with allergic rhinitis |
| CBP 067 | Regulatory submission targeted in 2009 | Antihistamine and antitussive combination | Oral suspension | Temporary relief of symptoms associated with cough and upper respiratory symptoms associated with allergies or a cold |
| CBP 069 | Regulatory submission targeted in 2009 | Antihistamine and antitussive combination | Oral suspension | Temporary relief of symptoms associated with cough and upper respiratory symptoms associated with allergies or a cold |

***SPECTRACEF Line Extensions***

*Overview*

SPECTRACEF is an integral part of Cornerstone s current sales strategy, as well as its sales growth strategy for the future. To protect and expand SPECTRACEF s market share, Cornerstone has developed SPECTRACEF 400 mg, a higher dose tablet for the adult market, and is developing Spectracef Once Daily, a new oral solid dosage form, and SPECTRACEF Suspension, an oral suspension for the pediatric market.

*SPECTRACEF 400 mg*

SPECTRACEF 400 mg is a single 400 mg tablet, twice-daily dosage of SPECTRACEF for which Cornerstone received approval from the FDA in July 2008. Cornerstone believes that patients will find taking one 400 mg tablet twice daily to be more convenient than taking two SPECTRACEF 200 mg tablets twice daily. SPECTRACEF 400 mg is indicated for acute bacterial exacerbation of chronic bronchitis and community-acquired pneumonia. Cornerstone expects to launch SPECTRACEF 400 mg in the fourth quarter of 2008.

Table of Contents

*SPECTRACEF Once Daily*

SPECTRACEF Once Daily is a single tablet, once-daily dosage of SPECTRACEF. Cornerstone filed an IND with the FDA in July 2008 for SPECTRACEF Once Daily, which has since been approved by the FDA, and expects to commence a clinical trial in the fourth quarter of 2008 to evaluate the pharmacokinetic profile of a formulation of SPECTRACEF Once Daily developed by Patheon Inc. If the results of this pharmacokinetic trial is favorable, Cornerstone expects to commence two clinical trials in the first quarter of 2009 to evaluate the safety and efficacy of this product candidate designed to form the basis for an NDA submission to the FDA in 2010 for the treatment of acute bacterial exacerbations of chronic bronchitis with COPD. Cornerstone is designing this trial as superiority, randomized studies of patients with acute bacterial exacerbation of chronic bronchitis. A superiority trial must show that the test product is statistically better than the comparator, which may be a placebo. Cornerstone anticipates that, if approved based on the results of these clinical trials, the FDA will grant SPECTRACEF Once Daily a three-year period of marketing exclusivity under the Hatch-Waxman Act.

Cornerstone believes that the once-daily dosage of this product candidate would be more convenient for patients than taking SPECTRACEF twice daily and would increase compliance. Among oral solid cephalosporins, only Cedax and Suprax have a once-daily dosage. Most macrolides and quinolones also have a once-daily dosage option.

*SPECTRACEF Suspension*

SPECTRACEF Suspension is an oral, liquid suspension of SPECTRACEF. Cornerstone expects to submit an NDA in 2009 for use of this product candidate by children with pharyngitis or tonsillitis based on the results of a number of previously conducted clinical trials. Two of these clinical trials compared the safety and efficacy of orally administered cefditoren pivoxil with an FDA-approved product, penicillin VK, using a non-inferiority design. Each clinical trial was a Phase III, randomized, double-blind, active-controlled, parallel-group, multicenter study of outpatients with streptococcal pharyngitis or tonsillitis. In the first clinical trial, 503 patients received either cefditoren pivoxil or penicillin VK. Of these, a total of 364 patients were considered microbiologically evaluable for efficacy at a post-therapy visit and 352 patients were microbiologically evaluable for efficacy at a subsequent follow-up visit. All 503 patients were included in the safety analyses. In the second clinical trial, 508 patients received either cefditoren pivoxil or penicillin VK. Of these, a total of 364 patients were considered microbiologically evaluable for efficacy at a post-therapy visit and 355 patients were microbiologically evaluable for efficacy at a subsequent follow-up visit. All 508 patients were included in the safety analyses. In each of these trials, cefditoren pivoxil was well tolerated with no significant adverse events reported. In the first trial, both treatment regimens were effective in resolving the clinical signs and symptoms of streptococcal pharyngitis or tonsillitis, but cefditoren pivoxil was statistically superior to penicillin VK in eradicating *Streptococcus pyogenes*. In the second trial, cefditoren pivoxil was equivalent to pencillin VK in resolving the clinical signs and symptoms of streptococcal pharyngitis or tonsillitis and in eradicating *Streptococcus pyogenes*.

In addition, Cornerstone expects to commence additional clinical trials in 2009 for SPECTRACEF Suspension in acute otitis media and submit an sNDA for this indication in 2010. Cornerstone is designing these clinical trials as superiority, randomized studies of patients with acute otitis media to evaluate the safety and efficacy of SPECTRACEF Suspension. If its NDA is approved, Cornerstone will have the option of launching SPECTRACEF Suspension for the pharyngitis and tonsillitis indications while the clinical trials in acute otitis media are ongoing. Cornerstone anticipates that, if approved based on the results of these clinical trials, the FDA will grant SPECTRACEF Suspension a three-year period of marketing exclusivity under the Hatch-Waxman Act for acute otitis media.

According to Wolters Kluwer Health, second and third generation oral cephalosporin suspensions generated approximately 7.8 million prescriptions in 2007 and approximately $750 million in sales, including suspension

products containing cefdinir that generated approximately 5.6 million prescriptions and approximately $580 million in sales.

Table of Contents

According to Wolters Kluwer Health, during the 54 week period ending May 16, 2008, pediatric specialists generated approximately 5 million second and third generation oral cephalosporin suspension prescriptions, or 64% of these prescriptions, and family practice specialists generated approximately 1.4 million prescriptions, or approximately 17% of these prescriptions.

*Proprietary Rights*

SPECTRACEF 400 mg, SPECTRACEF Once Daily and SPECTRACEF Suspension are covered by the same U.S. patents as SPECTRACEF 200 mg. Meiji also has applied for a U.S. patent that, if issued, would include claims to enhanced oral absorptivity for SPECTRACEF Once Daily. This patent application has been published and is currently pending. If issued, this patent would expire in 2023. Cornerstone s rights to market and develop SPECTRACEF 400 mg, SPECTRACEF Once Daily and SPECTRACEF Suspension are subject to its license arrangements with Meiji.

***Other Product Candidates***

*Methscopolamine/Antihistamine Product Candidate CBP 058*

*Overview and Development Status*

CBP 058 is a combination methscopolamine and antihistamine product candidate that Cornerstone is developing for the treatment of symptoms of allergic rhinitis. In 2007, Cornerstone met with the FDA regarding its plans to develop a methscopolamine and antihistamine product. Cornerstone plans to file an IND and to commence a clinical trial for the methscopolamine/antihistamine product candidate, CBP 058, in the first quarter of 2009 and submit an NDA in 2010. Cornerstone expects that the clinical studies for this product candidate will include a pharmacokinetic study in both fed and fasted states to establish a kinetic profile, as well as at least one clinical study in patients with allergic rhinitis to demonstrate safety and efficacy. Performing the pharmacokinetic study on both patients who have eaten a meal within the past hour and patients who have fasted overnight allows for a determination of the effect of food on the absorption of the drug. Because this product candidate is a combination product, the studies would compare the test product to its two individual components, and the test product must be statistically superior to both. If approved, Cornerstone believes this product candidate would be the first FDA-approved product containing methscopolamine with an indication associated with allergic rhinitis.

*Market Opportunity and Current Treatment Options*

According to AAAAI, allergic rhinitis has a strong link to other respiratory diseases including chronic sinusitis, middle ear infections, nasal polyps and bronchial asthma. The connection to bronchial asthma has caused great concern among allergists and immunologists. For example, a March 1999 article in *Discover* magazine described an analysis of over 1,200 asthmatics, approximately half of whom had rhinitis and half whom did not, in which those who had both rhinitis and asthma were more likely to have nighttime awakening due to asthma, 19.6 percent compared to 11.8 percent, to miss work because of asthma, 24.1 percent compared to 12.1 percent, and to meet the criteria for moderate to severe asthma, 60.2 percent compared to 51.2 percent. Additionally, asthmatics with rhinitis require more potent medications to control their symptoms. One potential explanation is that severe post-nasal drip triggers episodes of asthma. For example, researchers have found that inflammatory chemicals commonly found in the noses of people with allergic rhinitis drip into the lungs while they sleep, thus causing asthma to worsen.

According to Wolters Kluwer Health, oral solid methscopolamine combination products for the treatment of symptoms of respiratory diseases and allergies generated approximately 1.6 million prescriptions in 2007, representing a growth rate of 15% compared to 2006. In addition, second and third generation antihistamine and

antihistamine combination products generated a total of approximately 52 million prescriptions in 2007.

Current treatments for the symptoms of allergic rhinitis consist of both prescription and over-the-counter products. Prescription products include large second generation antihistamine branded families of products, such as Sanofi-Aventis U.S. LLC s Allegra® (fexofenadine), third generation antihistamine branded families of

Table of Contents

products, such as UCB, Inc. and Sanofi-Aventis U.S. LLC s Xyzal® (levocetirizine) and Schering-Plough Corporation s Clarinex® (desloratadine), and first generation antihistamine and antihistamine combination products, most of which are generic formulations. Over-the-counter products include first generation antihistamines, such as McNeil-PPC, Inc. s Benadryl® (diphenhydramine) and Schering-Plough Corporation s Chlor-Trimeton® (chlorpheniramine), and second generation antihistamines, such as Claritin and Zyrtec.

*Benefits of CBP 058*

If approved, CBP 058 will combine a less sedating antihistamine to combat the histamine released during an allergic reaction with an anticholinergic to relieve symptoms of post-nasal drip and other mucous secretions. This combination of therapies is not currently commercially available in a single tablet. Less sedating second and third generation prescription antihistamines do not have an anticholinergic option, and first generation antihistamine and anticholinergic combination products currently available on the market are more sedating.

Cornerstone anticipates that, if approved based on the results of clinical trials that it plans to conduct, the FDA will grant CBP 058 a three-year period of marketing exclusivity under the Hatch-Waxman Act. In addition, based on FDA precedent with respect to DESI II drugs that are clinically tested and submitted to the FDA for approval, Cornerstone expects that the FDA would require other methscopolamine products, including the first generation antihistamine and methscopolamine combinations currently available, to be removed from the market after a grace period. In such event, Cornerstone believes that CBP 058 would be the only methscopolamine product indicated for the symptoms of allergic rhinitis on the market that physicians could prescribe.

*Proprietary Rights*

Cornerstone has licensed the rights to market CBP 058 utilizing the Dynamic Variable Release® technology licensed from Neos. Dynamic Variable Release technology is covered under a pending U.S. patent application that if issued would expire in 2024. This licensed technology allows Cornerstone to formulate CBP 058 with one or more active pharmaceutical ingredients that require immediate activation followed by extended release of the remaining active pharmaceutical ingredients.

*Hydrocodone Cough Suppressant Product Candidates CBP 067 and CBP 069*

*Overview and Development Status*

CBP 067 and CBP 069 are extended-release antihistamine and antitussive, or cough suppressant, combination product candidates currently in development. Cornerstone expects that both of these product candidates will require only pharmacokinetic studies for approval. Pharmacokinetic studies are designed to establish the kinetic profile of the test product and compare this profile to the profile of already approved products. Cornerstone plans to submit applications for marketing approval for these product candidates in 2009 and, if approved, commercially launch the product candidates in 2010. If approved, these product candidates will compete directly in the hydrocodone cough suppressant market.

*Market Opportunity and Current Treatment Options*

Cough can adversely affect quality of life, leading patients to seek medical attention. Health care providers have a variety of treatment options. Non-productive cough is commonly treated with antitussive and antitussive combinations that do not contain an expectorant, such as guaifenesin. Antitussive combination products that treat non-productive coughs typically combine an antitussive, including hydrocodone, codeine or dextromethorphan, with antihistamines, including chlorpheniramine or brompheniramine, or decongestants, including pseudoephedrine or phenylephrine.

Dextromethorphan is available in both over-the-counter and prescription formulations. Hydrocodone, a centrally acting opioid antitussive, has been shown to be as effective as codeine but without gastrointestinal side effects.

According to Wolters Kluwer Health, in 2007, there were over 26 million prescriptions generated for oral antitussive and antitussive combinations without an expectorant. Of these, nearly 4.8 million were for

Table of Contents

Phenergan with codeine, which is available as a generic, and almost 3 million for UCB Pharma s Tussionex® (hydrocodone polistirex and chlorpheniramine polistirex), which is only available as a brand.

On September 28, 2007, the FDA announced its intention to take enforcement action against companies marketing unapproved prescription drug products containing the narcotic hydrocodone. The action did not affect hydrocodone formulations that have FDA approval. Only eight cough suppressants containing hydrocodone were approved by the FDA as of September 15, 2008. Any company marketing unapproved hydrocodone drug products was required to cease manufacturing such products on or before December 31, 2007, and cease further shipment in interstate commerce on or before March 31, 2008, although pharmacies could continue to sell their remaining inventory.

According to Wolters Kluwer Health, U.S. sales of prescription hydrocodone cough suppressants were $300 million in 2007, with over 9.75 million prescriptions written. Approximately 55% of those prescriptions were for products not approved by the FDA.

In addition, 66% of the sales and 30% of the prescriptions written in 2007 for hydrocodone cough suppressants were generated by Tussionex, an approved extended-release hydrocodone and antihistamine combination. With limited availability of approved hydrocodone products, Tussionex prescriptions have increased dramatically in 2008. According to Wolters Kluwer Health, in April 2008, the month after the FDA enforcement action went into effect, Tussionex prescriptions grew 34% and sales grew 46% as compared to April 2007. Despite being approved by the FDA in 1987, Tussionex does not face any generic competition and has no patent protection.

*Benefits of CBP 067 and CBP 069*

Most antitussive and antitussive combination products that are currently marketed are in an immediate-release formulation, meaning they must be dosed every four to six hours, which can be inconvenient. For example, patients may not be able to sleep through the night because their antitussive is not effective for more than four hours. Cornerstone believes that CBP 067 and CBP 069 could improve patients quality of life by providing more convenient twice-daily, longer lasting dosing.

*Proprietary Rights*

Cornerstone has licensed the rights to market CBP 067 and CBP 069 utilizing the Dynamic Variable Release technology and the Dynamic Time Release Suspension™ technology of Neos and the drug resin complex technology of Coating Place, Inc., or Coating Place. Cornerstone expects that these licensed technologies will allow Cornerstone to formulate CBP 067 and CBP 069 with one or more active pharmaceutical ingredients that require immediate activation followed by a sustained timed release of the remaining active pharmaceutical ingredients over a 12-hour period. Neos s Dynamic Variable Release technology is covered under a pending U.S. patent application that if issued would expire in 2024. Neos s Dynamic Time Release Suspension technology is covered under a pending U.S. patent application that if issued would expire in 2025. Coating Place s drug resin complex technology is covered under a pending U.S. patent application that if issued would expire in 2025.

**Sales and Marketing; Co-promotion Agreements**

***Sales and Marketing***

Cornerstone has built a commercial organization, consisting at September 15, 2008 of a respiratory-focused sales team that includes 49 sales representatives, five sales managers and one national sales director. Cornerstone s sales team is supported by marketing, market research and commercial operations professionals who are responsible for developing Cornerstone s brands, implementing strategies and tactical plans for sales force execution, performing business

analytics, leveraging commercial technology, overseeing sales operations and training Cornerstone s sales representatives.

Cornerstone representatives currently call on high-prescribing, respiratory-focused physicians and key retail pharmacies. Cornerstone believes this highly specialized approach provides it with the opportunity for greater

access to this group of health care professionals. It also increases Cornerstone s market coverage and frequency of detailing visits to this target audience. All representatives are required to provide management with quarterly business plans to ensure all resources are being utilized effectively. Cornerstone currently maintains a one to two-week call cycle for all promoted products and records calls into an internally built intranet system for information management.

Cornerstone believes that the current market opportunity for its products and the future opportunity for its pipeline of product candidates, if approved, will likely warrant the need for sales force expansion. Cornerstone expects to commence this expansion as FDA approval of a product candidate is obtained or expected to be obtained in the near future, revenues expand or Cornerstone obtains additional funding.

Cornerstone seeks to differentiate its products from its competitors by emphasizing the clinical advantages and favorable side effect profile for patients who are suffering from respiratory diseases or allergies. Cornerstone s marketing programs include patient co-payment assistance, health care provider education and information to further support patient compliance. In addition, Cornerstone has established a respiratory advisory board with varying specialties to assist in developing its corporate strategy for both its products and product candidates. National conventions and publication plans are also integral aspects of Cornerstone s overall marketing plan.

***Co-promotion Agreements***

Cornerstone seeks to enter into co-promotion arrangements to enhance its promotional efforts and sales of its products. Cornerstone may enter into co-promotion agreements with respect to its products that are not aligned with Cornerstone s respiratory focus or when it lacks sufficient sales force representation in a particular geographic area.

*Co-promotion Agreement with SJ Pharmaceuticals*

In March 2007 and June 2007, Cornerstone entered into co-promotion agreements with SJ Pharmaceuticals, LLC, or SJ Pharmaceuticals, to co-promote the ALLERX Dose Pack family of products and SPECTRACEF, respectively. Under these agreements, Cornerstone pays SJ Pharmaceuticals fees based on a percentage of the net profits of the ALLERX Dose Pack and SPECTRACEF products sold above a specified baseline based upon prescriptions by assigned, targeted prescribers within assigned sales territories. These targeted prescribers are mutually agreed upon by Cornerstone and SJ Pharmaceuticals prior to the start of each quarter.

SJ Pharmaceuticals sales representatives are located primarily in the southeastern United States. SJ Pharmaceuticals is required under the co-promotion agreements to maintain a trained sales force of at least 20 representatives to detail ALLERX Dose Pack and SPECTRACEF products and is required to maintain an incentive compensation plan to encourage superior performance by its sales representatives. SJ Pharmaceuticals promotes the ALLERX Dose Pack and SPECTRACEF products to primary care physicians, allergists, otolaryngologists, physician assistants, nurse practitioners, pharmacists and other specialists in SJ Pharmaceuticals assigned sales territories. Because SJ Pharmaceuticals only promotes to prescribers on its assigned, targeted prescriber list, Cornerstone sales representatives have no overlapping prescribers.

The ALLERX co-promotion agreement expires on March 28, 2010, unless extended by mutual agreement of the parties. The SPECTRACEF co-promotion agreement expires on June 13, 2010, unless extended by mutual agreement of the parties. Each co-promotion agreement contains customary provisions permitting termination based upon bankruptcy, insolvency and breach of the agreement. Each co-promotion agreement also can be terminated by either party without cause upon 60 days advance notice. Additionally, Cornerstone may terminate the SPECTRACEF co-promotion agreement at any time if SJ Pharmaceuticals is unable to increase SPECTRACEF sales above the specified baseline. If SJ Pharmaceuticals terminates a co-promotion agreement based upon Cornerstone s breach of such agreement, or Cornerstone terminates a co-promotion agreement without cause or, in the case of the

SPECTRACEF co-promotion agreement, Cornerstone terminates because SJ Pharmacueticals is unable to increase SPECTRACEF sales above the specified baseline, then SJ Pharmaceuticals is entitled to receive a termination fee for the six months following such termination, paid on

Table of Contents

a quarterly basis, equal to the average monthly amount paid by Cornerstone to SJ Pharmaceuticals during the six months immediately preceding such termination.

*Co-promotion Agreement with Atley Pharmaceuticals*

In April 2007, Cornerstone entered into a co-promotion agreement with Atley Pharmaceuticals to co-promote BALACET 325. In July 2008, Cornerstone and Atley Pharmaceuticals agreed to amend the co-promotion agreement to include APAP 325 and any other generic formulation of BALACET 325. Under the agreement, Cornerstone pays Atley Pharmaceuticals fees based on a percentage of the net profits from sales of BALACET 325, and any generic formulations thereof marketed by Cornerstone, above a specified baseline within assigned sales territories. The parties have agreed to revise the baseline semi-annually to ensure that the baseline is attainable using commercially reasonable efforts.

Atley Pharmaceuticals sales representatives are mainly located in the southeastern, southwestern and midwestern United States. Atley Pharmaceuticals is required under the co-promotion agreement to maintain a trained sales force of at least 40 representatives to detail BALACET 325 and generic formulations thereof and an incentive compensation plan to encourage superior performance by its sales representatives. Atley Pharmaceuticals promotes BALACET 325 and generic formulations thereof to pain specialists and primary care providers and other specialties within Atley Pharmaceuticals assigned sales territories. According to Wolters Kluwer Health, there has been a 35% increase in bottles dispensed from the first half of 2007 to the second half of 2007 within the sales territories where Atley Pharmaceuticals sales representatives promote the product.

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

**Trade, Distribution and Reimbursement**

***Trade Sales and Distribution***

Cornerstone s customers consist of drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the United States. It primarily sells products directly to drug wholesalers, which in turn distribute the products to retail drug stores, mass merchandisers and grocery store pharmacies. Cornerstone s top three customers, which represented 91% of gross sales in 2007, are all drug wholesalers and are listed below:

| | % of Gross Sales | | |
|---|---|---|---|
| **Customer** | **2007** | **2006** | **2005** |
| Cardinal Health | 43.2% | 36.7% | 45.1% |
| McKesson | 33.7% | 37.6% | 30.8% |
| AmerisourceBergen | 13.9% | 8.5% | 9.6% |

Consistent with industry practice, Cornerstone maintains a returns policy that allows its customers to return products within a specified period prior and subsequent to the expiration date. Occasionally, Cornerstone may also provide additional discounts to some customers to ensure adequate distribution of its products.

Cornerstone s trade distribution group actively markets Cornerstone s products to authorized distributors through regular sales calls. This group has many years of experience working with various industry distribution channels. Cornerstone management believes that its trade distribution group significantly enhances Cornerstone s commercial performance by ensuring product stocking in major channels across the country;

Table of Contents

continued follow-up with accounts and monitoring of product performance; successful product launch strategies; and partnering with customers on other value-added programs. Cornerstone s active marketing effort is designed to ensure proper distribution of its products so that patients prescriptions can be filled with the Cornerstone products that health care professionals prescribe.

Cornerstone relies on DDN, a third party logistics provider, for the distribution of Cornerstone s products to drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies. DDN ships Cornerstone s products from its warehouse in Memphis, Tennessee to Cornerstone customers throughout the United States as orders are placed through Cornerstone s customer service center.

***Reimbursement***

In the U.S. market, sales of pharmaceutical products depend in part on the availability of reimbursement to the patient from third-party payors, such as government health administration authorities, managed care providers and private insurance plans. All of Cornerstone s products are generally covered by managed care and private insurance plans. The status or tier within each plan varies but coverage is similar to other products within the same class of drugs. For example, SPECTRACEF is covered by private insurance plans similar to other marketed, branded cephalosporins. Some Medicare Part D plans also cover some or all of Cornerstone s products, but the amount and level of coverage varies from plan to plan. Cornerstone also participates in the Medicaid Drug Rebate program with the Centers for Medicare & Medicaid Services and submits all of its products for inclusion in this program. Coverage of Cornerstone s products under individual state Medicaid plans varies from state to state. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and reviewing different cost savings efforts, which could affect the reimbursement available for Cornerstone s products.

**Manufacturing**

Cornerstone currently outsources the manufacturing of all of its commercially available products and the formulation development of its product candidates for use in clinical trials to FDA-approved third parties. Cornerstone intends to continue to rely on third parties for its manufacturing requirements. Cornerstone provides regulatory and quality guidance to and oversight of its third-party manufacturers with respect to its products. Cornerstone also provides regular product forecasts to assist its third-party manufacturers with efficient production planning. Where possible and commercially reasonable, Cornerstone qualifies more than one source for manufacturing and packaging of its products to manage the risk of supply disruptions. In such circumstances, if one of Cornerstone s manufacturers or packagers were unable to supply Cornerstone s needs, Cornerstone would have an alternative source available for those products.

While some of Cornerstone s products do not have an alternative manufacturer qualified due to exclusivity provisions in the respective licensing agreements or based on other commercial considerations, Cornerstone believes there are other suppliers that could serve as replacements for the current manufacturers if the need arose. However, qualifying such a replacement manufacturer with the FDA could take a significant amount of time, and, as a result, Cornerstone would not be able to guarantee an uninterrupted supply of the affected product to its customers.

Cornerstone has entered into supply agreements with third-party manufacturers and packagers for each of its marketed products. Depending on the finished product presentation, some of its manufacturers also package the product. In other cases, the manufacturer supplies the bulk form of the product and Cornerstone packages

Table of Contents

the product through a separate third party. Important information about Cornerstone s material manufacturing and packaging agreements is summarized in the following table.

| Manufacturer/ Packager | Product | Term of Agreement |
|---|---|---|
| Bayer | Bulk tablets for the ALLERX Dose Pack family of products | July 2007 to June 2010; renews for successive one-year terms unless terminated by either party with six months prior written notice. |
| Meiji | SPECTRACEF API (cefditoren pivoxil) | October 2006 to September 2016; renews for successive one-year terms unless terminated with six months prior written notice. |
| | SPECTRACEF 400 mg | Ten years from the launch date of the product. |
| Patheon | SPECTRACEF 200 mg finished product | Product ordered from time to time on a purchase order basis. |
| Vintage | BALACET 325 and APAP 325 | July 2004 to June 2009; renew for one-year terms unless terminated with one year s prior written notice. |

Several of Cornerstone s products require the use of active pharmaceutical ingredients regulated by the DEA under the Controlled Substances Act. In these instances, DEA quota requirements regulate the procurement of these active pharmaceutical ingredients and products containing these active pharmaceutical ingredients by the manufacturer and packager. It is the responsibility of Bayer and Sovereign, the respective primary and backup manufacturers of bulk tablets for ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D and RESPIVENT-D, Legacy and Carton Service, the manufacturers of trade and sample packaging for ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX-D and RESPIVENT-D, and Vintage, the manufacturer of BALACET 325, APAP 325 and APAP 500, to request the necessary quota allocation from the DEA to meet Cornerstone s forecasted production requirements on an annual basis. However, the DEA has significant discretion in deciding how to allocate controlled substance quotas and whether to authorize a quota for Cornerstone. This discretion presents a potential risk to Cornerstone s supply chain. Cornerstone and its suppliers attempt to manage this risk through accurate product planning and timely quota submissions with appropriate allocation justifications to the DEA.

In producing Cornerstone s products, Cornerstone s manufacturers and packagers are also held to the FDA s cGMP requirements and other compliance regulations mandated by the FDA, the DEA and other regulatory authorities.

***Bayer Toll Manufacturing Agreement for ALLERX Dose Pack***

*Overview*

In June 2007, Cornerstone entered into a toll manufacturing agreement with Bayer pursuant to which Bayer is obligated to manufacture bulk tablets for the ALLERX Dose Pack family of products, including ALLERX PE-PM, ALLERX PE-AM, ALLERX DF-AM, ALLERX PM and ALLERX AM, in quantities ordered by Cornerstone.

*Fees*

Under this agreement, Cornerstone paid Bayer a one time set-up fee and is obligated to pay for the units delivered to Cornerstone pursuant to purchase orders delivered to Bayer.

Table of Contents

*Minimum Purchase Requirements*

An additional one-time cost of up to $135,000 will be due on December 31, 2009 if Cornerstone fails to meet the minimum annual purchase requirement of 27.0 million tablets per year for 2008 and 2009.

*Indemnification*

Bayer agreed to indemnify Cornerstone against any breach of the agreement or the quality agreement by Bayer or any act or omission by Bayer in the performance of the agreement, except to such extent such claim is the result of any act or omission by Cornerstone relating to the performance of this agreement. Cornerstone agreed to indemnify Bayer against any breach of the agreement or the quality agreement by Cornerstone or the sale, use, or distribution of the product or the finished product by Cornerstone, except to such extent such claim is the result of any act or omission by Bayer relating to the performance of this agreement.

*Term and Termination*

The term of the agreement extends to June 2010 and will be automatically renewed for successive one-year terms unless either party provides written notice of termination at least six months prior to the end of the then current term. The Agreement contains customary provisions permitting termination based upon bankruptcy, insolvency and breach of the agreement. In addition, Cornerstone may terminate the agreement upon 30 days written notice in the event of a change of the site of manufacture of any product to any site that has not been approved by Cornerstone. If Bayer undergoes a change of control as defined in the agreement, Cornerstone may terminate the agreement upon 30 days notice to Bayer. If Cornerstone terminates the agreement for any reason before June 1, 2009, other than for Bayer s breach of the agreement, Cornerstone shall be obligated to make an early termination payment to Bayer. Finally, Cornerstone may terminate upon 30 days notice if a regulatory agency does not approve the finished product for marketing, a regulatory agency withdraws marketing approval or Cornerstone otherwise terminates the commercial sale of finished product. If termination is initiated by Bayer, any such termination shall not be effective until Cornerstone has arranged for the product to be manufactured by another contract manufacturer, not to exceed 18 months from Bayer s written notice of termination.

***Meiji License and Supply Agreement***

This agreement is described below under the section entitled Cornerstone s Business License and Collaboration Agreements Meiji SPECTRACEF License and Supply Agreement beginning on page 211 of this proxy statement/prospectus.

***Patheon SPECTRACEF Finished Product Orders***

From time to time Cornerstone engages Patheon to manufacture SPECTRACEF 200mg. The parties have not entered into a long term manufacturing agreement. Instead, Cornerstone orders quantities of SPECTRACEF from time to time on a purchase order basis. The terms and conditions of such purchase orders are specified at the time of purchase and generally include, but are not limited to, the type and specifications of the product, the quantity, the price, payment terms, indemnity terms and a time and place of delivery.

***Vintage Manufacturing Agreement for APAP 325 and APAP 500***

*Overview*

In July 2004, Cornerstone entered into a manufacturing agreement with Vintage at the same time Cornerstone entered into an asset purchase agreement pursuant to which Cornerstone acquired rights to APAP 325 and APAP 500. Pursuant to the manufacturing agreement, Vintage is obligated to manufacture BALACET 325 products, APAP 325 products and APAP 500 products in quantities ordered by Cornerstone.

Table of Contents

*Fees*

Under this agreement, Cornerstone is obligated to pay Vintage for the units delivered to Cornerstone pursuant to purchase orders delivered to Vintage.

*Exclusivity*

Pursuant to the manufacturing agreement, Vintage granted Cornerstone the exclusive right to manufacture the products named in the agreement and not to subcontract or make any other agreements concerning the products. Also, during the term of the agreement, Vintage agreed to exclusively supply Cornerstone, and Cornerstone agreed to not to enter into any agreement with any other person for the manufacture of the products.

*Indemnification*

Vintage agreed to indemnify Cornerstone against any loss resulting from any breach of the agreement by Vintage or any negligence in the manufacture of the products. Cornerstone agreed to indemnify Vintage against any loss resulting from any third party claims made against Vintage which arise from Cornerstone s formulation, handling, distribution or sale of the products. In addition, the parties will indemnify each other in connection with the challenges to certain intellectual property rights under such party s control.

*Term and Termination*

The term of the agreement expires June 2009 and will be automatically renewed for successive one-year terms unless either party provides written notice of termination at least one year prior to the end of the then current term. The Agreement contains customary provisions permitting termination based upon breach of the agreement.

**Intellectual Property**

Cornerstone s success depends in part on its ability to obtain and maintain proprietary protection for its product candidates, technology and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing its proprietary rights. Cornerstone s policy is to seek to protect its proprietary position by, among other methods, filing U.S. and foreign patent applications related to its proprietary technology, inventions and improvements that are important to the development of its business and obtaining, where possible, assignment of invention agreements from employees and consultants. Cornerstone also relies on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain its proprietary position.

***Patents***

As of September 15, 2008, Cornerstone owned or exclusively licensed a total of four issued U.S. patents and three pending U.S. patent applications. Cornerstone s patent portfolio, which is set forth in the following table, includes patents and patent applications with claims directed to composition of matter, formulations of its products and product candidates and methods of use of its products and product candidates to treat particular indications.

Table of Contents

| Patent Number | Issued Patents | Product | Ownership | Filed | Issued | Expiration |
|---|---|---|---|---|---|---|
| 4,839,350 | Cephalosporin compounds and the production thereof | SPECTRACEF | Licensed | 04/07/1987 | 6/13/1989 | 04/07/2009 |
| 5,958,915 | Antibacterial composition for oral administration | SPECTRACEF | Licensed | 10/14/1996 | 09/28/1999 | 10/14/2016 |
| 6,270,796 | Antihistamine/ decongestant regimens for treating rhinitis | ALLERX Dose Pack(1) | Licensed | 10/29/1997 | 08/07/2001 | 10/29/2017 |
| 6,843,372 | Antihistamine/ decongestant regimens for treating rhinitis | ALLERX Dose Pack PE, ALLERX 10 Dose Pack, ALLERX 30 Dose Pack | Licensed | 05/04/2001 | 01/18/2005 | 05/04/2021 |

| Application Number | Pending Patents | Product | Ownership | Filed | Published | Expiration |
|---|---|---|---|---|---|---|
| 20040115272 | Amorphous cefditoren pivoxil composition and process for producing the same | SPECTRACEF | Licensed | 04/26/2002 | 06/17/2004 | 04/26/2022 |
| 20080015241 | All day rhinitic condition treatment regimen | ALLERX Dose Pack DF | Owned | 07/13/2006 | 01/17/2008 | 07/13/2026 |
| 20080185313 | Medicament regimen for treating bronchitis or lower respiratory tract condition | None | Owned | 02/05/2007 | 08/07/2008 | 02/05/2027 |

(1) AlleRx Dose Pack was reformulated in March 2008 and is currently marketed under Patent No. 6,843,372

All patents were filed with and subsequently issued or published by the United States Patent and Trademark Office

Other than SPECTRACEF, patent protection is not available for composition of matter claims directed to the active pharmaceutical ingredients of Cornerstone s current products and product candidates. As a result, Cornerstone primarily relies on the protections afforded by its formulation and method of use patents. Method of use patents, in particular, are more difficult to enforce than composition of matter patents because of the risk of off-label sale or use of the subject compounds.

For information about the patents and patent applications that Cornerstone owns or exclusively licenses that it considers to be most important to the protection of its products and product candidates, see Proprietary Rights under each of the products and product candidates described above under Marketed Products and Product Development Pipeline.

Table of Contents

***Trade Secrets***

Cornerstone may rely, in some circumstances, on trade secrets to protect its technology. However, trade secrets can be difficult to protect. Cornerstone seeks to protect its proprietary technology and processes, in part, by confidentiality agreements with its employees, scientific advisors and consultants. Cornerstone also seeks to preserve the integrity and confidentiality of its data and trade secrets by maintaining physical security of its premises and physical and electronic security of its information technology systems. While Cornerstone has confidence in these individuals, organizations and systems, agreements or security measures may be breached, and Cornerstone may not have adequate remedies for any such breach. In addition, Cornerstone s trade secrets may otherwise become known or be independently discovered by competitors. To the extent that Cornerstone s consultants, contractors or collaborators use intellectual property owned by others in their work for Cornerstone, disputes may arise as to the rights in related or resulting know-how or inventions.

***Trademarks***

Cornerstone uses trademarks on all of its marketed branded products and believes that having distinctive marks is an important factor in marketing these products. Cornerstone has registered with the United States Patent and Trademark Office its ALLERX, DECONSAL and BALACET trademarks, among others. SPECTRACEF is owned by Meiji and licensed to Cornerstone for sales and marketing purposes in the United States.

**License and Collaboration Agreements**

***Meiji SPECTRACEF License and Supply Agreement***

*Overview*

On October 12, 2006, Cornerstone entered into a license and supply agreement, as subsequently amended, with Meiji that grants Cornerstone an exclusive, nonassignable U.S. license to manufacture and sell SPECTRACEF, using cefditoren pivoxil supplied by Meiji, for its currently approved therapeutic indications and to use Meiji s SPECTRACEF trademark in connection with the sale and promotion of SPECTRACEF for its currently approved therapeutic indications. The agreement also extends these rights to additional products and additional therapeutic indications of products containing cefditoren pivoxil supplied by Meiji that are jointly developed by Meiji and Cornerstone and which Meiji and Cornerstone agree to have covered by the agreement.

*Fees, Milestones and Royalties*

In consideration for the licenses Meiji granted to Cornerstone, Cornerstone agreed to pay Meiji a nonrefundable license fee of $6 million in six installments over a period of five years from the date of the agreement. If a generic cefditoren product is launched in the United States prior to October 12, 2011, Cornerstone will be released from its obligation to make any further license fee payments due after the date of launch, unless, as agreed in a July 27, 2007 letter agreement between Cornerstone and Meiji, Cornerstone successfully launches SPECTRACEF 400 mg, SPECTRACEF Once Daily or SPECTRACEF Suspension and sales of these products substantially lessen the generic product s adverse effect on SPECTRACEF sales. If Cornerstone is able to launch one of these SPECTRACEF line extensions and substantially mitigate the effect of generic competition, it will be required to continue paying Meiji a reasonable amount of the license fee as mutually agreed by the parties.

The license and supply agreement also requires Cornerstone to make quarterly royalty payments based on the net sales of the cefditoren pivoxil products covered by the agreement. Cornerstone is required to make these payments for a period of ten years from the date the particular product is launched by Cornerstone.

*Exclusive Supplier and Minimum Purchase Obligation*

Under the license and supply agreement, Meiji is Cornerstone s exclusive supplier of cefditoren pivoxil. Pursuant to the current draft of the written addendum to the license and supply agreement, which is expected

Table of Contents

to become effective in September 2008, Cornerstone will be obligated to make aggregate combined purchases of API, SPECTRACEF 200 mg, SPECTRACEF 400 mg and sample packs of SPECTRACEF 400 mg from Meiji exceeding specified dollar amounts annually over a five year period. These purchase obligations are described in the section entitled Cornerstone s Business License and Collaboration Agreements Meiji Addendum to License and Supply Agreement beginning on page 213 of this proxy statement/prospectus. If Cornerstone does not meet its minimum purchase requirement in a given year, Cornerstone must pay Meiji an amount equal to 50% of the shortfall in that year. These minimum purchase requirements cease to apply if a generic cefditoren product is launched in the United States prior to October 12, 2011.

*Indemnification*

Pursuant to the license and supply agreement, Meiji agrees to indemnify Cornerstone against any actions arising out of a breach of the agreement or any actions by third parties due to a defect in the API if such defect is attributable to Meiji in the manufacture of the API. Cornerstone agrees to indemnify Meiji against any actions arising out of a breach of the agreement or any actions by third parties resulting from the use of the API and manufacture, use, marketing, distribution or sale of SPECTRACEF. Notwithstanding the above, if any third party claims that SPECTRACEF caused adverse reactions despite the product being in strict compliance with specifications that were approved by the FDA and applicable cGMP and was not misbranded or otherwise altered, Cornerstone is not obligated to indemnify Meiji and Cornerstone has the right to deduct 50% of any costs incurred in connection with such claims from the license fee and royalty otherwise payable to Meiji.

*Term and Termination*

The term of the license and supply agreement is described in the section entitled Cornerstone s Business License and Collaboration Agreements Meiji Addendum to License and Supply Agreement beginning on page 213. In addition to customary provisions permitting termination based upon bankruptcy protection, insolvency and breach of the agreement, Meiji may immediately terminate the agreement if Cornerstone undergoes a change in control as defined in the agreement without Meiji s consent, which may not be unreasonably withheld; ceases selling SPECTRACEF for a period of 60 days, unless the cessation is due to a force majeure event or a failure or delay by Meiji in supplying cefditoren pivoxil; or promotes, markets or sells, either directly or indirectly through a third party, any pharmaceutical products in the United States of the same therapeutic class as cefditoren pivoxil. On or after April 1, 2012, Cornerstone may terminate the agreement with 270 days prior written notice if a generic cefditoren product is launched in the United States that substantially lessens Cornerstone s sales of SPECTRACEF. If the agreement is terminated by Cornerstone based upon Meiji s bankruptcy, insolvency or breach of the agreement, or by Meiji based upon Cornerstone undergoing a change of control, then Cornerstone has the right to continue selling the product from its existing inventory and to manufacture and sell additional product using its existing inventory of API, in each case for a period of 180 days after such termination.

*Joint Product Development*

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

***Meiji Letter Agreement and Formulation Agreement***

On July 27, 2007, Meiji and Cornerstone entered into a letter agreement whereby they agreed that the terms and conditions of the license and supply agreement apply to SPECTRACEF 400 mg, SPECTRACEF Suspension and

SPECTRACEF Once Daily once Cornerstone receives the necessary FDA approvals for these SPECTRACEF line extensions, provided that there is a reduction to the royalty paid by Cornerstone to Meiji to compensate for the development expenses. The letter agreement requires Cornerstone to bear all of the development costs for SPECTRACEF 400 mg. The letter agreement further provides that Cornerstone has the

exclusive right to manufacture and sell these SPECTRACEF line extensions in the United States for their approved therapeutic indications and to use the SPECTRACEF trademark in connection with the sale of these SPECTRACEF line extensions for their approved therapeutic indications. The parties agreed to add a production site for the manufacture of SPECTRACEF 200 mg tablets and Meiji would pay Cornerstone a reimbursement fee for expenses to be incurred by Cornerstone for regulatory work and filings in connection with adding the production site.

Under a further letter agreement dated January 11, 2008, or the formulation agreement, Cornerstone and Meiji agreed on the allocation of expenses related to the development of SPECTRACEF Suspension and SPECTRACEF Once Daily, and Meiji made payments for the development of these product candidates to Cornerstone in installments through June 30, 2008.

***Meiji Joint Development Agreement***

On February 11, 2008, Cornerstone and Meiji entered into a joint development agreement, which supplemented the July 27, 2007 letter agreement and the January 11, 2008 formulation agreement. Under the joint development agreement, Meiji granted Cornerstone the exclusive right to develop SPECTRACEF Suspension and SPECTRACEF Once Daily in the United States. Under the joint development agreement, Meiji and Cornerstone agreed on a development plan for SPECTRACEF Suspension and SPECTRACEF Once Daily; agreed that Cornerstone would bear all expenses related to the development of these SPECTRACEF line extensions except as provided in the formulation agreement; and confirmed that, once approved, the terms and conditions of the license and supply agreement apply to the SPECTRACEF line extensions, unless otherwise provided in the joint development agreement.

*Term and Termination*

The term of the joint development agreement runs concurrently with the term of the license and supply agreement, unless earlier terminated. In addition to customary provisions permitting termination based upon bankruptcy protection, insolvency and breach of the agreement, either party may terminate the agreement after consultation with the other party and with 30 days prior written notice, if it becomes impossible or impracticable from a reasonable pharmaceutical point of view to continue the development of SPECTRACEF Suspension and SPECTRACEF Once Daily. If Cornerstone terminates the joint development agreement based on impossibility or impracticability from a reasonable pharmaceutical point of view, Cornerstone s rights to SPECTRACEF Suspension and SPECTRACEF Once Daily under the July 27, 2007 letter agreement and the joint development agreement will terminate, and Cornerstone would be required to assist Meiji with further development of those product candidates if so requested by Meiji.

***Meiji Addendum to License and Supply Agreement***

*Overview*

In August 2008, Cornerstone and Meiji entered into a verbal agreement to expand the scope of the license and supply agreement. The parties are currently negotiating a written addendum to the license and supply agreement, which Cornerstone expects will supersede the verbal agreement in September 2008. Cornerstone believes the negotiations to be substantially complete and that the material terms of such written addendum will be as described below. Meiji has begun manufacturing SPECTRACEF 400 mg pursuant to the verbal agreement pending the parties execution of the written addendum.

Under the latest draft of the written addendum, Meiji will grant Cornerstone an exclusive right to sell SPECTRACEF 200 mg and SPECTRACEF 400 mg in the United States. The terms and conditions of the license and supply agreement continue to remain in full force and effect, except to the extent expressly varied or amended by the written addendum.

213

Table of Contents

*Fees and Royalty Payments*

Cornerstone does not expect to have to pay any additional license fees for the additional licenses; however, the latest draft of the written addendum requires Cornerstone to make quarterly royalty payments based on the net sales covered by the addendum for a period of 10 years from the launch date for each product.

*Exclusivity and Minimum Purchase Requirements*

Under the latest draft of the written addendum, Meiji will be Cornerstone s exclusive supplier of SPECTRACEF 400 mg during the 10-year period so long as Meiji is able to supply 100% of Cornerstone s requirements for this product. Additionally, Meiji will be a non-exclusive supplier of SPECTRACEF 200 mg during the 10-year period. Cornerstone is required to purchase from Meiji combined amounts of API, SPECTRACEF 200 mg, SPECTRACEF 400 mg and sample packs of SPECTRACEF 400 mg exceeding $15.0 million for the first year beginning with the commercial launch of SPECTRACEF 200 mg or SPECTRACEF 400 mg manufactured by Meiji, whichever is earlier, $20.0 million for year two, $25.0 million for year three, $30.0 million for year four and $35.0 million for year five. If Cornerstone does not meet its minimum purchase requirement in a given year, Cornerstone must pay Meiji an amount equal to 50% of the shortfall in that year. Cornerstone expects to exceed the minimum purchase requirements. If Cornerstone is unable to meet the minimum purchase requirements, the parties agree to discuss in good faith measures they can take to address the situation. If Cornerstone launches the Once-Daily product, then the parties will discuss in good faith if any adjustments are required to the minimum purchase requirements.

*Indemnification*

Under the latest draft of the written addendum, Meiji agrees to indemnify Cornerstone against any actions arising out of a breach of the agreement or any actions by third parties due to a defect in the SPECTRACEF 200 mg and SPECTRACEF 400 mg if such defect is attributable to Meiji in the manufacture, storage, handling or shipment of SPECTRACEF 200 mg and SPECTRACEF 400 mg. Cornerstone agrees to indemnify Meiji against any actions arising out of a breach of the agreement or any actions by third parties resulting from the use of SPECTRACEF 200 mg and SPECTRACEF 400 mg and manufacture, use, marketing, distribution or sale of the product. Notwithstanding the above, if any third party claims that the product caused adverse reactions despite the product being in strict compliance with specifications that were approved by the FDA and applicable cGMP and was not misbranded or otherwise altered, and there is no negligence or willful misconduct by Cornerstone in marketing and selling SPECTRACEF 200 mg and SPECTRACEF 400 mg, Cornerstone is not obligated to indemnify Meiji and Cornerstone has the right to deduct 50% of any costs incurred in connection with such claims from the royalty otherwise payable to Meiji.

*Term*

The term of the license and supply agreement, as amended by the latest draft of the written addendum, continues on a product-by-product basis until the expiration of 10 years from the launching date of each product. In addition, the term, on a product-by-product basis, shall automatically renew for subsequent one-year periods unless either party gives the other party six months prior written notice of its intention not to renew.

***Pharmaceutical Innovations ALLERX 372 Patent License Agreement***

*Overview*

On August 31, 2006, Cornerstone entered into a license agreement with Pharmaceutical Innovations that, as subsequently amended, provides for an exclusive license in the United States and Puerto Rico and a nonexclusive

license in all other markets to manufacture, package, market, distribute and otherwise exploit ALLERX Dose Pack products that are covered by claims under the 372 Patent, by corresponding foreign patents and foreign patent applications and by certain Pharmaceutical Innovations know-how related to those ALLERX Dose Pack products. Cornerstone also has the right to sublicense its rights under the license agreement to third parties. The 372 Patent expires May 4, 2021. On June 13, 2008, the U.S. Patent and

Table of Contents

Trademark Office received a request from Vision to re-examine the 372 Patent. On August 21, 2008, the U.S. Patent and Trademark Office ordered the re-examination of the 372 Patent. These re-examination proceedings are more fully discussed in the section entitled Cornerstone s Business Legal Proceedings beginning on page 232 of this proxy statement/prospectus.

*Royalties*

Cornerstone pays Pharmaceutical Innovations royalties based on net sales per calendar year of each product covered by the licensed Pharmaceutical Innovations patents or know-how. Cornerstone has agreed to a minimum annual royalty payment to Pharmaceutical Innovations throughout the term of the agreement. Royalties are payable with respect to the licensed patents until the earlier of the date all of the licensed patents expire or the date all of the licensed patents are determined to be invalid by a court or other governmental authority and such determination is no longer subject to appeal. Royalties are payable with respect to licensed know-how for a further period of seven years after the expiration of Cornerstone s obligation to pay royalties with respect to the licensed patents.

*Infringement by Third Parties and Indemnification*

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

Each party is obligated to indemnify the other party from all claims arising out of any claim that the technology of the other party infringes any intellectual property of a third party. The party indemnifying the other party is permitted to control the defense of such action.

*Term and Termination*

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

***Neos Development, License and Services Agreement Methscopolamine/Antihistamine Product***

*Overview*

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

215

Table of Contents

*Fees, Milestones and Royalties*

Under the agreement, Cornerstone is obligated to pay Neos a minimum fee of approximately $1.8 million for its performance of the development work under the agreement, plus hourly fees related to development work performed by Neos personnel as reflected in a mutually agreed development plan or otherwise approved by Cornerstone.

In consideration for Neos s exclusive license of patent-pending Dynamic Variable Release technology and related know-how in connection with the methscopolamine and antihistamine combination product, CPB 058, Cornerstone is obligated to pay royalties determined as a percentage of net sales of any licensed product.

*Exclusivity*

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

*Indemnification*

Under the agreement, Neos is obligated to indemnify Cornerstone against all losses incurred in connection with third party claims arising out of Neos s breach of the agreement, the manufacture, delivery, storage, handling and use of the product, any infringement claim concerning intellectual property, or any negligence, recklessness or willful misconduct of Neos, provided that Neos will not indemnify for losses due to Cornerstone s negligence, recklessness or willful misconduct or Cornerstone s breach of the agreement. Cornerstone is obligated to indemnify Neos against all losses incurred in connection with third party claims arising out of Cornerstone s breach of the agreement, or any negligence, recklessness or willful misconduct of Cornerstone, provided that Cornerstone will not indemnify for losses due to Neos s negligence, recklessness or willful misconduct or Cornerstone s breach of the agreement.

*Term and Termination*

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

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

Table of Contents

***Neos and Coating Place Development and Manufacturing Agreement Hydrocodone Cough Suppressant Products***

*Overview*

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

*Fees, Milestones and Profit Sharing*

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

*Product Development, Regulatory and Commercialization Expenses*

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

*Exclusivity*

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

*Indemnification*

Under the agreement, Cornerstone is obligated to indemnify Neos and Coating Place against actions arising out of any breach of the agreement by Cornerstone and the sale, distribution or marketing of the product. Neos is obligated to indemnify Cornerstone and Coating Place against actions arising out of any breach of the agreement by Neos. Coating Place is obligated to indemnify Cornerstone and Coating Place against actions arising out of any breach of the agreement by Coating Place. The indemnification obligations contained in the agreement do not extend to any loss which is the direct result of negligence, intentional misconduct of the party seeking indemnification or any matter for which the party seeking indemnification is obligated to provide indemnification to the other party.

*Term and Termination*

The term of this agreement is 15 years from the date the first product is approved by the FDA, with the opportunity for one or more additional five-year successive terms, as mutually agreed by the parties.

The Agreement contains customary provisions permitting termination based upon bankruptcy, insolvency and breach of the agreement. Additionally, if Cornerstone has failed to commercially launch the first product in the United States or Canada by the fifth anniversary of the agreement, any party may immediately terminate the

Table of Contents

agreement by written notice to the other parties. Additionally, upon the failure of clinical testing with respect to Neos s proposed formulation for the first product or Cornerstone s receipt of an FDA rejection of Cornerstone s drug approval application with respect to the first product, if Cornerstone decides not to proceed with additional work or studies, then Cornerstone has the right to immediately terminate the agreement by written notice to the other parties.

***Neos Products Development Agreement***

*Overview*

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

*Fees, Milestones and Royalties*

Under the agreement, Cornerstone forgave debt owed by Neos totaling $500,000. Neos, at it own expense, is obligated to develop the first product up to and including completion of the first clinical study in humans. Cornerstone is obligated to pay Neos hourly fees related to development work performed by Neos personnel as reflected in a mutually agreed development plan or otherwise approved by Cornerstone. In addition, Cornerstone is obligated to pay certain milestone payments for additional work by Neos, including work performed in connection with regulatory approval and patent issuance. In connection with a manufacturing agreement, Cornerstone will be obligated to pay royalties determined as a percentage of net sales of any licensed product.

*Exclusivity*

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

*Indemnification*

Cornerstone is obligated to indemnify and hold Neos harmless from any actions arising out of a third party claim resulting from any breach by Cornerstone of any term contained in the agreement, or the willful infringement by Cornerstone of a third party s intellectual property rights related to the products. Neos is obligated to indemnify and hold Cornerstone harmless from any actions arising out of any breach by Neos of any term contained in the agreement or the willful infringement of any patent or misappropriation of any trade secret by Neos in connection with the agreement or the performance of Neos s obligations except to the extent arising out of the willful infringement by Cornerstone of a third party s patent rights or misappropriation of any trade secret.

*Term and Termination*

The agreement expires on December 31, 2026. In addition to customary provisions permitting termination based upon bankruptcy protection, insolvency and breach of the agreement, this agreement may be terminated

Table of Contents

upon written notice by either party to the other that federal or state regulatory authorities with jurisdiction over a party and the products has effected, or will effect at a time certain, changes to the regulations or have instituted one or more enforcement actions that can, in the determination of the relevant party, be reasonably expected to result in the commercial infeasibility of the objectives of the agreement. The agreement may also be terminated upon written notice by Cornerstone to Neos if Cornerstone determines that continued investment in the development or commercialization of the products is not commercially advisable.

***Sovereign Supply and Marketing Agreement for Sovereign s Hyoscyamine Products***

*Overview*

In May 2008, Cornerstone, through its wholly owned subsidiary Aristos, entered into a supply and marketing agreement with Sovereign pursuant to which Cornerstone obtained the exclusive right to market, sell and distribute in the United States three of Sovereign s generic products, each containing the API hyoscyamine.

*Profit Share*

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

*Indemnification*

Pursuant to the agreement, Sovereign agreed to indemnify Cornerstone against any losses arising from any action by a third party to the extent such losses arise from a material breach of the agreement, however, Sovereign is not obligated to indemnify Cornerstone to the extent such losses arise from the gross negligence or willful misconduct of Cornerstone or a material breach by Cornerstone. Cornerstone agreed to indemnify Sovereign against any losses arising from any action by a third party to the extent such losses arise from a material breach of the agreement, however, Cornerstone is not obligated to indemnify Sovereign to the extent such losses arise from the gross negligence or willful misconduct of Sovereign or a material breach by Sovereign.

*Term and Termination*

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

***Capellon Verbal Agreement for Capellon s Products***

*Overview*

Cornerstone, through its wholly owned subsidiary Aristos, is marketing and distributing HYOMAX DT tablets in the United States pursuant to a verbal agreement between Cornerstone and Capellon. The parties are currently negotiating a written license agreement and Cornerstone expects that a written agreement will supersede the verbal agreement in

September 2008.

Cornerstone believes the negotiations to be substantially complete and that the material terms of such written agreement will be as described below.

Table of Contents

*Profit Sharing*

Under this most recent draft of the written agreement, Cornerstone will be obligated to use commercially reasonable efforts to market, sell and distribute the HYOMAX DT product manufactured by Capellon to wholesalers and distributors in the United States in return for a share of the net profits realized from the sale of the products.

*Indemnification*

Pursuant to the most recent draft of the written agreement, Capellon will agree to indemnify Cornerstone against (i) any losses arising from any action by a third party to the extent such losses arise from a material breach of the agreement, however, Capellon will not be obligated to indemnify Cornerstone to the extent such losses arise from (i) the gross negligence or willful misconduct of Cornerstone or (ii) a material breach by Cornerstone. Cornerstone will agree to indemnify Capellon against (i) any losses arising from any action by a third party to the extent such losses arise from a material breach of the agreement, however, Cornerstone will not be obligated to indemnify Capellon to the extent such losses arise from (i) the gross negligence or willful misconduct of Capellon or (ii) a material breach by Capellon.

*Term and Termination*

The proposed initial term of the most recent draft of the written agreement will expire April 30, 2011 and will be automatically renewed for successive one-year terms unless either party provides written notice of termination at least 90 days prior to the end of the then current term. In addition to customary provisions permitting termination based upon bankruptcy protection, insolvency and breach of the agreement, Cornerstone will be able to immediately terminate the agreement by written notice if Sovereign undergoes a change of control as defined in the agreement or if the FDA or other regulatory authority orders the discontinuance for any reason of the commercial sale of the products. Notwithstanding the expiration or termination of the Agreement, Cornerstone may continue to sell all HYOMAX DT product in its inventory until such inventory is exhausted unless commercial sale of the products has been discontinued pursuant to orders of the FDA or other regulatory authority.

***Vintage Asset Purchase Agreement Propoxyphene/Acetaminophen Products***

*Overview*

In July 2004, Cornerstone entered into an asset purchase agreement, as subsequently amended, with Vintage, pursuant to which Cornerstone obtained the rights, title and interest to BALACET 325 and APAP 500. Under this agreement, Cornerstone has all rights to promotion, marketing, sale, distribution and manufacturing of these two products. In addition, Vintage granted Cornerstone the right to market and sell an authorized generic version of BALACET 325. Cornerstone s authorized generic version of BALACET 325 is referred to herein as APAP 325.

*Fees and Royalties*

Cornerstone paid an $8,000,000 fee in connection with the asset purchase agreement and is obligated to pay Vintage a royalty equal to a percentage of net sales of BALACET 325, APAP 500 and APAP 325 each calendar quarter.

*Indemnification*

Pursuant to the asset purchase agreement, Vintage agreed to indemnify Cornerstone against any actions arising out of a breach of the agreement, the gross negligence or willful misconduct of Vintage and liabilities related to the products incurred prior to the closing. Cornerstone agreed to indemnify Vintage against any actions arising out of a breach of

the agreement, the gross negligence or willful misconduct of Vintage and Cornerstone s manufacturing, storage, marketing, promotion, sale or distribution of the products after closing.

Table of Contents

***Pliva APAP 500 Supply and Marketing Agreement***

In September 2005, Cornerstone entered into a supply and marketing agreement with Pliva, granting Pliva the exclusive right to market Cornerstone s propoxyphene napsylate and acetaminophen 100mg/500mg product, APAP 500, in the United States and its territories. Under this agreement, Cornerstone handles the regulatory processes and Vintage supplies Pliva with the APAP 500 product. Under this agreement, Pliva is obligated to pay Cornerstone a percentage of net sales each calendar quarter through the term of the agreement.

The current term of this agreement expires December 31, 2008. Cornerstone has given notice to Pliva that at the end of the current term, it will terminate the agreement. At the end of the term, Cornerstone will commence sales and marketing of this product directly.

**Competition**

The pharmaceutical industry, including the respiratory market in which Cornerstone principally competes, is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Cornerstone faces potential competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Cornerstone s current products compete, and any product candidates that it successfully develops and commercializes will compete, with existing therapies and new therapies that may become available in the future.

Many of Cornerstone s competitors may have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than Cornerstone does. These competitors also compete with Cornerstone in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, Cornerstone s programs or advantageous to its business. In many cases, products that compete with Cornerstone s currently marketed products and product candidates have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. The principal competitors to Cornerstone s products are more fully discussed in the section entitled Risks Related to Cornerstone Cornerstone faces competition, which may result in others discovering, developing or commercializing products before or more successfully than Cornerstone beginning on page 62 of this proxy statement/prospectus. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Cornerstone s ability to remain competitive in the marketplace is also impacted by its ability to compete successfully with other specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. These established companies may have a competitive advantage over Cornerstone due to their size and financial resources.

The key competitive factors affecting the success of all of Cornerstone s products and product candidates, if approved, are and are likely to continue to be efficacy, safety, convenience, price, the availability of patent protection or regulatory marketing exclusivity, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Cornerstone s commercial opportunity could be reduced or eliminated if its competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are more convenient or are less expensive than any products that Cornerstone may develop. Cornerstone s competitors also may obtain FDA or other regulatory approval for their products more rapidly than Cornerstone may obtain approval for its products. In addition,

Cornerstone s ability to compete may be affected because in some cases insurers or other third-party payors seek to encourage the use of generic products, which may have the effect of making branded products less attractive, from a cost perspective, to buyers.

Table of Contents

***Marketed Products***

Cornerstone s currently marketed products face significant competition from a wide range of branded and generic products for the same therapeutic indications. Upon loss of regulatory marketing exclusivity or patent protection or as a result of design-around strategies that allow for generic product introduction prior to the expiration of key product patents, Cornerstone is potentially subject to competition from generic versions of its branded products. Generics are typically priced at lower levels than branded products and may substantially erode prescription demand and sales of Cornerstone s branded products. The specific competitive conditions affecting SPECTRACEF and ALLERX are more fully discussed in the sections entitled Marketed Products beginning on page 192 of this proxy statement/prospectus. Cornerstone s generic products are also subject to competition from equivalent generic products introduced by other pharmaceutical companies. Such competition may adversely impact the sales volume and pricing of Cornerstone s generic products and Cornerstone s ability to profitably market these products.

***Product Candidates***

Given that Cornerstone is developing product candidates based on currently marketed drug compounds, some or all of the products in Cornerstone s product pipeline, if approved, may face competition from generic and branded formulations of these existing drugs. Cornerstone s ability to successfully market and sell the products in its pipeline will depend on the extent to which its newly formulated product candidates have the benefit of patent protection or some other form of regulatory marketing exclusivity or are meaningfully differentiated from these existing drugs or new competitive formulations of these drugs offered by third parties. In addition, Cornerstone s product candidates, if approved, will compete with other branded and generic drugs approved for the same therapeutic indications, approved drugs used off label for such indications and novel drugs in clinical development. The competitive conditions affecting the products in Cornerstone s product pipeline is more fully discussed in the section entitled Product Development Pipeline beginning on page 199 of this proxy statement/prospectus.

**Regulatory Matters**

The research, testing, manufacture and marketing of drug and biologic products are extensively regulated in the United States and abroad. In the United States, drugs and biologics are subject to rigorous regulation by the FDA. The FDCA and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, packaging, labeling, advertising and promotion, sampling and distribution of pharmaceutical and biologic products. Failure to comply with applicable regulatory requirements may subject Cornerstone to a variety of administrative or judicially imposed sanctions, including the FDA s refusal to accept new applications or to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

***United States Approval Process for New Drug Applications***

Before marketing a new drug product in the United States, the product sponsor must first demonstrate that the product is safe, effective and properly manufactured, and must obtain FDA approval in the form of an approved NDA, sNDA or ANDA. As a matter of FDA enforcement policy, limited categories of drugs that have historically been marketed without such approval also may remain on the market subject to the risk that the FDA may at any time require the product sponsors to obtain approval for the products or remove them from the market. In seeking FDA approval for its product candidates, Cornerstone intends to follow the development and approval pathway permitted under the FDCA that it believes will maximize the commercial opportunities for its product candidates.

Satisfaction of FDA approval requirements typically takes a minimum of several years, and the actual time required may be substantially longer depending upon the type of approval required, the complexity of the product, the target disease or the nature and extent of required clinical trials or other data requirements. Compliance with FDA approval requirements will require substantial investments of time, money and

Table of Contents

corporate resources and may significantly delay or even prevent Cornerstone from marketing potential products. Success in early stage clinical trials does not necessarily assure success in later stage clinical trials. Data obtained from clinical trials are not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in marketing or sales restrictions on the product or even complete withdrawal of the product from the market. Line extensions or other significant changes to an approved product (e.g., adding a new dosage strength) also require submission and prior FDA approval of a supplemental application including additional clinical or other data required to demonstrate the safety and efficacy of the changed product.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the development, approval, manufacturing and marketing of drug products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect Cornerstone s business and its products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

*New Drug Application*

The steps ordinarily required before a new pharmaceutical product may be marketed in the United States include the conduct of preclinical laboratory tests, animal tests and formulation studies; submission to the FDA of an application for IND, which must become effective prior to commencement of human clinical testing; the conduct of adequate and well-controlled clinical trials in accordance with good clinical practices to establish that the product is safe and effective for the indication for which FDA approval is sought; the preparation and submission of the NDA; satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity; and FDA review and approval of the marketing application.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of compounds for testing must comply with federal regulations and requirements. The results of preclinical testing are submitted to the FDA as part of an IND during the IND stage of development and as part of the NDA.

An IND must become effective prior to the commencement of clinical testing of a drug in humans. An IND will automatically become effective 30 days after receipt by the FDA if the FDA has not commented on or questioned the application during this 30-day waiting period. If the FDA has comments or questions, these may need to be resolved to the satisfaction of the FDA prior to commencement of clinical trials. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. The IND process can result in substantial delay and expense.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations and requirements, under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the safety and effectiveness criteria to be evaluated. Each protocol for an unapproved drug involving testing human subjects in the United States must be submitted to the FDA as part of the IND. The trial protocol and informed consent information for subjects in clinical trials must be submitted to institutional review boards for approval.

Clinical trials to support new drug product applications for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase I, the initial introduction of the product

candidate into healthy human subjects or patients, the product is tested to assess metabolism; pharmacokinetics; safety, including side effects associated with increasing doses; and, at times, pharmacological actions. Phase II usually involves trials in a limited patient population to determine dosage

tolerance and optimum dosage, identify possible adverse effects and safety risks and provide preliminary support for the efficacy of the product in the indication being studied.

If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to evaluate further clinical efficacy and to test further for safety within an expanded patient population, typically at geographically dispersed clinical trial sites. Phase I, Phase II or Phase III testing of any product candidates may not be completed successfully within any specified time period, if at all. Furthermore, the FDA, an institutional review board or Cornerstone may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

After successful completion of the required clinical testing for a drug, generally an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include, among other things, the results of all clinical and preclinical safety testing and a compilation of the data relating to the product s pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of NDAs are additionally subject to substantial application user fees, currently exceeding $1.1 million, the fee for submission of supplemental applications exceeds $580,000 and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently exceeding $65,000 per product and up to $392,000 per establishment. These fees are typically increased annually.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended and reauthorized by the FDAAA, an NDA or supplement to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDAAA also authorizes the FDA to require sponsors of currently marketed drugs to conduct pediatric studies if the drug serves a substantial number of pediatric patients and adequate pediatric labeling could benefit such patients, the drug would provide a meaningful therapeutic benefit for pediatric patients or the absence of pediatric labeling could pose a risk to pediatric patients. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the drug for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The review process is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA normally also will conduct a pre-approval inspection to ensure the manufacturing facility, methods and controls are adequate to preserve the drug s identity, strength, quality, purity and stability and are in compliance with regulations governing current good manufacturing practices. In addition, the FDA usually conducts audits of the clinical trials for NDAs and efficacy supplements to ensure that the data submitted reflects the data generated by the clinical sites.

If the FDA s evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA and issue a complete response letter. The complete response letter outlines the deficiencies in the submission and often requires additional testing or information in order for the FDA to reconsider the application. Even after submitting this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of an NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

If the FDA s evaluations are favorable, the FDA may issue an approval letter or, in some cases, a complete response letter followed by an approval letter. A complete response letter generally contains a statement that the application is not yet ready for approval and describes the specific deficiencies and, if applicable,

recommended actions an applicant might take to get the application ready for approval. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require post-approval trials and surveillance to monitor the drug s safety or efficacy and may impose other conditions, including labeling restrictions and restricted distribution, which can materially impact the potential market and profitability of the drug.

*Supplemental New Drug Application*

Once an NDA is in effect, the drug sponsor must notify the FDA of any change in an approved product beyond variations already allowed in the marketing approval. Significant changes generally require prior approval of an sNDA, which may require additional clinical trials or other data required to demonstrate that the product as modified remains safe and effective. For example, Cornerstone submitted, and received approval for, an sNDA with respect to SPECTRACEF 400 mg since this product represents a change in strength from the 200 mg version of SPECTRACEF. Other modifications which would require sNDA approval include substantive changes in labeling, the addition of one or more new indications for use, a new dosage form (e.g., introduction of a new extended-release formulation), and significant manufacturing changes including a new manufacturing site. Such supplements, referred to as Prior Approval Supplements, must contain information to demonstrate that the modified product will remain safe, effective, and consistently manufactured. FDA does not require duplication of previously-submitted data that remain applicable to proposed NDA modification.

According to the FDA s guidelines and PDUFA agreements, the FDA should review sNDAs within six months of submission. Once an sNDA is submitted to the FDA the company receives from the FDA a filing date, which is the date the FDA received and processed the filing for documentation. This notification from the FDA to the company usually also includes an action date which is the date the FDA sets to indicate approval or non-approval of the submission. An applicant may ask the FDA to expedite its review for public health reasons, such as a drug shortage.

The process of obtaining FDA approval for an sNDA may be expensive and time-consuming, and if not approved, the product will not be allowed to be marketed as modified.

*Abbreviated New Drug Application*

The ANDA route of approval provides for marketing of a generic drug product that has the same active pharmaceutical ingredients in the same strengths and dosage form as an NDA-approved reference listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug products, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

When a drug product is approved through an NDA, its sponsor must list with the FDA each patent with claims that cover the product or an approved use of the product. Upon NDA approval, the drug product and associated patent information are published in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited as the reference listed drug by subsequent ANDA applicants. The ANDA applicant must supply information demonstrating its generic product meets the sameness and bioequivalence requirements described above, as well as detailed manufacturing information. Additionally, ANDA applicants must certify to the FDA with respect to each patent listed for the reference listed product in the Orange Book. Specifically, the applicant must certify that:

the required patent information has not been filed;

the listed patent has expired;

the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or

Table of Contents

the listed patent is invalid or unenforceable or will not be infringed by the manufacture, use or sale of the new product.

A certification that the new product will not infringe the already approved product s listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If there are no listed patents, or all patents have expired, ANDA approval will not be delayed.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders with a detailed statement of the factual and legal basis for the applicant s belief that the patents are invalid, unenforceable or not infringed once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV notice automatically prevents the FDA from approving the ANDA for up to 30 months from the date of receipt of notice by the patent holder. The Hatch-Waxman Act explicitly encourages generic challenges to listed patents by providing for a 180-day period of generic product exclusivity for the first generic applicant to challenge a listed patent for an NDA-approved drug. Thus, many if not most successful new drug products are subject to generic applications and patent challenges prior to the expiration of all listed patents.

*Section 505(b)(2) New Drug Applications*

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA s findings of safety and efficacy of an approved product, or on published literature, in support of its application.

Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products, or for the initial approval of drugs previously marketed without NDAs/ANDAs under the Prescription Drug Wrap-Up program discussed below. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA s findings with respect to particular preclinical studies or clinical trials conducted for an approved product, or upon published clinical and scientific data. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is subject to existing exclusivity for the referenced product and is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired; until any nonpatent exclusivity, such as exclusivity for obtaining approval of a new chemical entity listed in the Orange Book for the referenced product, has expired; and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months or a decision or settlement in the infringement case finding the patents to be invalid, unenforceable or not infringed.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA s interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), this could delay or even prevent the FDA from approving any

Section 505(b)(2) NDA that Cornerstone submits.

Table of Contents

***Prescription Drug Wrap-Up***

The FDCA, enacted in 1938, was the first statute requiring premarket approval of drugs by the FDA. These approvals, however, focused exclusively on safety data. In 1962, Congress amended the FDCA to require that sponsors demonstrate that new drugs are effective, as well as safe, in order to receive FDA approval. These amendments also required the FDA to conduct a retrospective evaluation of the effectiveness of the drug products that the FDA approved between 1938 and 1962 on the basis of safety alone. The agency contracted with the National Academy of Science/National Research Council, or the NAS/NRC, to make an initial evaluation of the effectiveness of many drug products. The FDA s administrative implementation of the NAS/NRC reports was the DESI.

Drugs that were not subject to applications approved between 1938 and 1962 were not subject to DESI review. For a period of time, the FDA permitted these drugs to remain on the market without approval. In 1984, however, spurred by serious adverse reactions to one of these products, Congress urged the FDA to expand the new drug requirements to include all marketed unapproved prescription drugs. The FDA created a program, known as the Prescription Drug Wrap-Up, to address these remaining unapproved drugs. Most of these drugs contain active pharmaceutical ingredients that were first marketed prior to the enactment of the FDCA in 1938. Cornerstone believes that several of its marketed pharmaceutical products fall within this category.

The FDA asserts that all drugs subject to the Prescription Drug Wrap-Up are on the market illegally and are subject to FDA enforcement action at any time. There are several narrow exceptions. For example, both the original statutory language of the FDCA and the 1962 amendments include grandfather provisions exempting certain drugs from the new drug requirements. The 1938 clause exempts drugs that were on market prior to the passage of the FDCA in 1938 and that contain the same representations concerning the conditions of use as they did prior to passage of the Act. The 1962 amendments exempt, in certain circumstances, drugs that have the same composition and labeling as they had prior to the passage of the 1962 amendments. The FDA and the courts have interpreted these two exceptions very narrowly. As to drugs marketed over the counter, the FDA exempts through regulation products that have been determined to be generally recognized as safe and effective and have been used to a material extent and for a material time.

The FDA has adopted a risk-based enforcement policy that prioritizes enforcement of the new drug approval requirement for unapproved drugs that pose a safety threat, lack evidence of effectiveness, prevent patients from pursuing effective therapies or are marketed fraudulently. In addition, the FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug approval requirement. Once the FDA issues an approved NDA for one of the drug products at issue or completes the efficacy review for that drug product, it may require other manufacturers to also file an NDA or an ANDA for that same drug in order to continue marketing it in the United States. While the FDA generally provides sponsors a one-year grace period, it is not statutorily required to do so.

***Post-Approval Compliance Requirements and Changes to Approved Products***

Whatever route of approval is used to gain FDA marketing approval, all marketed drug products are subject to certain post-approval requirements, including requirements for adverse event reporting and a range of periodic reporting and recordkeeping requirements. Drug manufacturers also must comply with the FDA s cGMP regulations, which govern all phases of the drug production process, and manufacturing facilities are subject to periodic FDA inspection for cGMP compliance. In addition, the FDA strictly regulates the promotional claims that may be made about prescription drug products and biologics. In particular, the FDA requires substantiation of any claims of superiority of one product over another, including that such claims be proven by adequate and well-controlled head-to-head clinical trials. To the extent that market acceptance of Cornerstone s products may depend on their superiority over existing therapies, any restriction on Cornerstone s ability to advertise or otherwise promote claims of superiority, or requirements to conduct

additional expensive clinical trials to provide proof of such claims, could negatively affect the sales of Cornerstone s products or its costs. Violation of any FDA requirements could result in enforcement actions, such as withdrawal of approval, product recalls, product seizures, injunctions, total or partial suspension of

Table of Contents

production or distribution, fines, consent decrees, civil penalties and criminal prosecutions, which could have a material adverse effect on Cornerstone s business.

Cornerstone must also notify the FDA of any change in an approved product beyond variations already allowed in the marketing approval. Once an NDA is in effect (including a 505(b)(2) NDA), significant changes such as a change in labeling, the addition of one or more new indications for use, a new dosage or strength of a drug or a change in the way Cornerstone manufactures a drug, generally require prior approval of an sNDA, which may require additional clinical trials or other data required to demonstrate that the product as modified remains safe and effective. Any modification of an ANDA-approved product that would cause the product to no longer be identical to its listed reference product requires prior approval in the form of a new NDA or 505(b)(2) NDA. Approvals of labeling or manufacturing changes may be expensive and time-consuming, and if not approved, the product will not be allowed to be marketed as modified.

***Marketing Exclusivity and Patent Term Restoration***

Under the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same API. The Hatch-Waxman Act prohibits the submission of an ANDA or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusivity period. However, submission of an ANDA or Section 505(b)(2) NDA containing a Paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Although protection under the Hatch-Waxman Act will not prevent the submission or approval of another full NDA, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosage forms, routes of administration, or strengths of an existing drug, or for a new use, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application. Cornerstone currently expects to seek three-year marketing exclusivity for SPECTRACEF Once Daily. This exclusivity would not prevent the approval of another application if the applicant has conducted its own adequate and well controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of a generic product that did not incorporate the exclusivity protected changes of the approved drug product.

***Pediatric Exclusivity***

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patent term. This six-month exclusivity may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued Written Request for such a study. Cornerstone plans to work with the FDA to determine the need for pediatric studies for its product candidates and may consider attempting to obtain pediatric exclusivity for some of its product candidates.

***Foreign Regulation***

Approval of a product by comparable regulatory authorities may be necessary in foreign countries prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. The approval procedure varies among countries and can involve requirements for additional testing. The time required may differ from that required for FDA approval. Although there are some procedures for unified filings for some European countries, such as the sponsorship of the country which first granted marketing approval, in general each

country has its own procedures and requirements, many of which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from foreign regulatory authorities after the relevant applications are filed.

Table of Contents

***Regulation of Controlled Substances***

Cornerstone sells products that are controlled substances as defined in the Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, labeling, packaging, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing an initial registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, including distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics and other designated substances. Reports must also be made for thefts or significant losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, so-called DEA Form 222, with copies provided to the DEA. Because hydrocodone and propoxyphene are Schedule II controlled substances, they are subject to the DEA s production and procurement quota scheme. The DEA establishes annually aggregate quotas for how much hydrocodone and propoxyphene may be produced in total in the United States based on the DEA s estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amounts of these substances that the DEA allows to be produced in the United States each year are allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. Cornerstone and its contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including propoxyphene for use in BALACET 325, APAP 325 and APAP 500, and hydrocodone for use in the Hydrocodone Cough Suppressants. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Cornerstone s, or its contract manufacturers , quota of an API may not be sufficient to meet commercial demand or complete clinical trials. Any delay or refusal by the DEA in establishing Cornerstone s, or its contract manufacturers , quota for controlled substances could delay or stop Cornerstone s clinical trials or product launches, which could have a material adverse effect on Cornerstone s business, financial position and results of operations.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on Cornerstone s business, results

of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Individual states also regulate controlled substances, and Cornerstone and its contract manufacturers will be subject to state regulation on distribution of these products.

Table of Contents

***Hazardous Materials***

Cornerstone relies on third parties to assist it in developing and manufacturing all of its products and does not directly handle, store or transport hazardous materials or waste products. The development and manufacturing activities performed by third parties at Cornerstone s request may involve the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. Cornerstone relies on its third parties to comply with all applicable federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. Cornerstone does not expect the cost of complying with these laws and regulations to be material to it.

**Pharmaceutical Pricing and Reimbursement**

Cornerstone s ability to commercialize its products successfully depends in significant part on the availability of adequate coverage and reimbursement from third-party payors, including governmental payors such as the Medicare and Medicaid programs, MCOs, and private health insurers. Third-party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. Cornerstone may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of its products, in addition to the costs required to obtain FDA approvals. Even with these studies, Cornerstone s products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may decide not to provide coverage and reimbursement for its product candidates, in whole or in part. If third-party payors approve coverage and reimbursement, the resulting payment rates may not be sufficient for Cornerstone to sell its products at a profit.

Political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental changes. There have been, and Cornerstone expects there will continue to be, legislative and regulatory proposals to change the health care system in ways that could significantly affect Cornerstone s business. Cornerstone anticipates that the United States Congress, state legislatures and the private sector will continue to consider and may adopt health care policies intended to curb rising health care costs. These cost containment measures could include, for example:

- controls on government funded reimbursement for drugs;
- controls on payments to health care providers that affect demand for drug products;
- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;
- weakening of restrictions on imports of drugs; and
- expansion of use of managed care systems in which health care providers contract to provide comprehensive health care for a fixed cost per person.

Under the Medicare Part D prescription drug benefit, which took effect in January 2006, Medicare beneficiaries can obtain prescription drug coverage from private plans that are permitted to limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class. Under this program, Cornerstone s products may be excluded from formularies and may be subject to significant price competition that depresses the prices it is able to charge. Cornerstone believes that it is likely that private managed care plans will follow Medicare coverage and reimbursement policies.

Outpatient pharmaceuticals sold to state administered Medicaid programs are subject to the national Medicaid drug rebate program. In order to have their drugs covered by state Medicaid programs, pharmaceutical companies must enter into an agreement under which they agree to pay a rebate to the states which is determined on the basis of a specified percentage of the average manufacturer price or the difference between the average manufacturer price and the best price. Pharmaceutical companies must also enter into a similar agreement with the U.S. Department of Veterans Affairs to have their drugs covered by state Medicaid programs, and some states may impose supplemental rebate agreements. Cornerstone is a party to these types of pricing agreements with respect to its currently marketed products.

Table of Contents

Cornerstone may also face competition for its products from lower-priced products from foreign countries that have placed price controls on pharmaceutical products. Proposed federal legislative changes may expand consumers ability to import lower-priced versions of competing products from Canada and other countries. In August 2007, the United States House of Representatives passed a measure that would permit more imports of prescription drugs, but the United States Senate has not yet approved it. If this proposal or similar proposals become law, Cornerstone s products may be subjected to increased price competition from lower priced imported drugs. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, Cornerstone expects other states and local governments to launch importation efforts. The importation of foreign products that compete with Cornerstone s own products could negatively impact its business and prospects.

Cornerstone is unable to predict what additional legislation, regulations or policies, if any, relating to the health care industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on its business. Any cost containment measures, including those listed above, or other health care system reforms that are adopted could impair Cornerstone s ability to set prices that cover its costs, constrain its ability to generate revenue from government funded or private third party payors, limit the revenue and profitability of its potential customers, suppliers and collaborators and impede its access to capital needed to operate and grow. Any of these circumstances could significantly limit Cornerstone s ability to operate profitably.

**Fraud and Abuse Regulation**

A number of federal and state laws and related regulations, loosely referred to as fraud and abuse laws, are used to prosecute health care providers, suppliers, physicians and others that fraudulently or wrongfully obtain reimbursement for health care products or services from government health programs, such as Medicare and Medicaid. These laws apply broadly and may constrain Cornerstone s business and the financial arrangements through which it markets, sells and distributes its products. These laws and regulations include:

*Federal Anti-Kickback Law.* The anti-kickback law contained in the federal Social Security Act is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay, or to solicit or receive, direct or indirect remuneration, in order to induce business reimbursed under a federal health care program, including Medicare and Medicaid. The term remuneration was intended to be and has been interpreted broadly and includes both direct and indirect compensation. Both the party offering and paying remuneration and the recipient may be found to have violated the statute. Courts have interpreted the anti-kickback law to cover any arrangement where one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals, regardless of whether there are also legitimate purposes for the arrangement. There are narrow exclusions authorizing arrangements that strictly comply with specified safe harbor criteria, but many legitimate transactions fall outside of the scope of any safe harbor standard, although that does not necessarily mean the arrangement will be subject to penalties under the anti-kickback statute. Penalties for federal anti-kickback violations are severe, including up to five years imprisonment, individual and corporate criminal fines, exclusion from participation in federal health care programs and civil monetary penalties in the form of treble damages plus $50,000 for each violation of the statute. It is possible that government regulators may find that Cornerstone s arrangements do not comply with this broad and often ambiguous law, to the extent it is determined that the statute is implicated by any of Cornerstone s arrangements.

*Stark Law.* The federal Statute on Limitations of Certain Physician Referrals, commonly referred to as the Stark Law, prohibits physician referrals for designated health services to entities in which the referring physician or an immediate family member has a financial interest, either through an ownership or investment interest or a compensation arrangement, unless the arrangement falls within a specific, narrow exception. Manufacturers and suppliers are prohibited from submitting and receiving federal health care program

reimbursement for products or services sold as a result of prohibited referrals. Violations of the statute can result in civil monetary penalties and exclusion from federal

Table of Contents

heath care programs. It is possible that Cornerstone s physician customers may have certain financial interests prohibited by the Stark Law.

*State Laws.* Various states have enacted laws and regulations comparable to the federal fraud and abuse laws and regulations. These state laws may apply to items or services reimbursed by any third-party payor, including private, commercial insurers and other payors. Moreover, these laws vary significantly from state to state and, in some cases, are broader than the federal laws. This increases the costs of compliance and the risk that the same arrangements may be subject to different compliance standards in different states.

**Corporate Organization**

Cornerstone is comprised of Cornerstone BioPharma Holdings, Inc., or Holdings, and its subsidiaries. Holdings was incorporated in Delaware in 2005. Cornerstone s operations are performed primarily by a subsidiary of Holdings, Cornerstone BioPharma, Inc., which was incorporated in Nevada in 2004 as Cornerstone Pharmaceuticals, Inc. Holdings acquired Cornerstone BioPharma, Inc. in 2005 from Cornerstone Biopharma Holdings, Ltd., a company under common control with Holdings.

**Employees**

As of September 15, 2008, Cornerstone had 78 full-time and five part-time employees, 65 of whom were engaged in marketing and sales; four of whom were engaged in research, development and regulatory affairs; and 14 of whom were engaged in management, administration and finance. None of Cornerstone s employees are represented by a labor union or covered by a collective bargaining agreement, and Cornerstone has not experienced any work stoppages. Cornerstone believes that relations with its employees are good.

**Properties**

In August 2004, Cornerstone entered into a lease agreement with Regency Park Corporation to lease its corporate headquarters. In January 2005, Cornerstone and Regency Park Corporation agreed to amend the lease agreement to add additional office space and adjust the annual rent accordingly. Currently, the corporate headquarters occupies approximately 7,800 square feet of office space and is located at 2000 Regency Parkway, an office complex in Cary, North Carolina. The lease has five-year term expiring in October 2009. Cornerstone paid an annual rent under this lease of approximately $157,000 during 2007. In addition to rent, Cornerstone is obligated to pay certain operating expenses and taxes. Cornerstone is currently in negotiations with the landlord under this lease concerning the terms and conditions that would apply to an early termination of the lease in connection with the relocation of Cornerstone s corporate headquarters as described below.

In May 2008, Cornerstone entered into a lease agreement with Crescent Lakeside, LLC for a new corporate headquarters, which will occupy approximately 14,900 square feet of office space. The new corporate headquarters will be located at 1255 Crescent Green in the Crescent Lakeside office complex, in Cary, North Carolina. The lease has an initial term that commences in December 2008 and expires in March 2016. Cornerstone also has an option to renew the lease for an additional five-year term through March 2021. Initial annual base rent under the lease is approximately $350,000 with annual rent increases of approximately three percent. In addition to rent, Cornerstone is obligated to pay certain operating expenses and taxes.

**Legal Proceedings**

In November 2006, Cornerstone was named as a defendant in an action filed in New York County, New York by Adams captioned *Adams Respiratory Therapeutics, Inc. (f/k/a Adams Laboratories, Inc.) v. Cornerstone BioPharma,*

*Inc. and Carolina Pharmaceuticals, Inc.*, Supreme Court of the State of New York, New York County, Index No. 603969/2006. The complaint alleged breach of contract concerning a settlement agreement between Cornerstone and Adams dated January 14, 2005. The complaint also alleged claims concerning the settlement agreement for account stated, fraudulent misrepresentation and negligent misrepresentation. The complaint sought damages ranging from approximately $910,000 to an unspecified amount in excess of $2.5 million. Cornerstone filed an answer to the complaint in which it denied the material allegations of the

Complaint and asserted counterclaims against Adams for breach of contract concerning the settlement agreement. Cornerstone s counterclaims sought damages in excess of $2 million. Following mediation in March 2008, the parties reached an agreement to settle all matters between them, which resulted in the parties execution of a new settlement agreement in May 2008. The litigation was dismissed, subject to the filing of a motion by Adams to reinstate the litigation on or before October 15, 2008 in the event of a default by Cornerstone and Carolina Pharmaceuticals under the new settlement agreement. Under the terms of the new settlement agreement, Cornerstone and Carolina Pharmaceuticals agreed to pay Reckitt Benckiser, Inc., the parent of Adams, $1.5 million, of which $1.0 million had been paid by the end of June 2008 and the remaining $500,000 is due and payable by the end of September 2008.

Prior to March 2008, Cornerstone used a different formulation for ALLERX 10 Dose Pack and ALLERX 30 Dose Pack that Cornerstone believes was protected under claims in the U.S. patent number 6,270,796, or the 796 Patent. Cornerstone and J-Med Pharmaceuticals, Inc., or J-Med, the licensor of the 796 Patent, have asserted infringements of the 796 Patent in litigation with each of Everton Pharmaceuticals, LLC, Breckenridge Pharmaceuticals, Inc., and Vision, and manufacturers and related parties of each, alleging that those parties had infringed the 796 Patent by making, using, selling, offering for sale or importing into the United States pharmaceutical products intended as generic equivalents to the former formulation of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack protected under claims in the 796 Patent. Everton and Breckenridge entered into settlement agreements in January 2007 and July 2007, respectively, and agreed to cease selling the infringing products. In October 2007, Cornerstone and J-Med filed an action in the U.S. District Court for the Eastern District of North Carolina against Vision and Nexgen Pharma, Inc. captioned *Cornerstone BioPharma, Inc. and J-Med Pharmaceuticals, Inc. v. Vision Pharma, LLC and Nexgen Pharma, Inc.*, No. 5:07-CV-00389-F. In this action, Cornerstone and J-Med alleged that the product known as VisRx infringes the 796 Patent. On November 19, 2007, Cornerstone and J-Med filed an amended complaint in which they asserted claims against Vision s principals, Sander Busman, Thomas DeStefano and Michael McAloose. On November 30, 2007, defendants moved to stay the litigation pending the re-examination of the 796 Patent. The Court granted defendants motion and stayed the litigation pending the re-examination of the 796 Patent on February 15, 2008. Separately, the U.S. Patent and Trademark Office ordered a re-examination of the 796 Patent as a result of a third-party request for ex parte re-examination.

In proceedings before a re-examination examiner in the U.S. Patent and Trademark Office, the examiner rejected claims of the 796 Patent as failing to satisfy novelty and non-obviousness criteria for U.S. patent claims. J-Med appealed to the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences, or Board of Patent Appeals, on June 13, 2008, seeking reversal of the examiner s rejections. On the same date, J-Med filed additional documents with the U.S. Patent and Trademark Office for review by the examiner. If the examiner does not reverse his prior rejections, then the Board of Patent Appeals will act on the case and can take various actions, including affirming or reversing the examiner s rejections in whole or part, or introducing new grounds of rejection of the 796 Patent claims. If the Board of Patent Appeals thereafter affirms the examiner s rejections, J-Med can take various further actions, including requesting reconsideration by the Board of Patent Appeals, filing a further appeal to the U.S. Court of Appeals for the Federal Circuit or instituting a reissue of the 796 Patent with narrowed claims. The further proceedings involving the 796 Patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the 796 Patent.

On June 13, 2008, counsel for Vision filed in the U.S. Patent and Trademark Office a request for re-examination of certain claims under the 372 Patent, which Cornerstone believes covers ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30. Counsel for Cornerstone reviewed the request for re-examination and the patents and publications cited by counsel for Vision, and Cornerstone s counsel have concluded that valid arguments exist for distinguishing the claims of the 372 Patent over the references cited in the request for re-examination. On August 21, 2008, the U.S. Patent and Trademark Office determined that a substantial new question of patentability was raised by the patents and publications cited by Vision. Cornerstone will have the opportunity in coordination with the patent owner, Pharmaceutical Innovations, to present substantive arguments

supporting the patentability of the claims issued in the 372 Patent. If the re-examination examiner in the U.S. Patent and Trademark Office rejects claims of the 372 Patent, Pharmaceutical Innovations may appeal to the Board of Patent Appeals to seek reversal of the examiner s rejections. If Pharmaceutical Innovations did not

**Table of Contents**

receive relief from the Board of Patent Appeals, Pharmaceutical Innovations could file a further appeal to the U.S. Court of Appeals for the Federal Circuit or could institute a reissue of the 372 Patent with narrowed claims. The further proceedings involving the 372 Patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the 372 Patent.

In February 2008, Cornerstone filed a Notice of Opposition before the Trademark Trial and Appeal Board in relation to Application No. 77/226,994 filed in the U.S. Patent and Trademark Office by Vision, seeking registration of the mark VisRx. The opposition proceeding is captioned *Cornerstone BioPharma, Inc. v. Vision Pharma, LLC,* Opposition No. 91182604. In April 2008, Vision filed an Answer to Notice of Opposition and Counterclaims in which it requested cancellation of U.S. Registrations No. 3,384,232 and 2,448,112 for the mark ALLERX owned by Cornerstone. Vision did not request monetary relief. Cornerstone responded to the counterclaims by Vision on May 16, 2008. Discovery in this proceeding is now underway. Cornerstone intends to defend its interests vigorously against the counterclaims asserted by Vision.

On May 15, 2008, the U.S. Patent and Trademark Office sent written notice to Cornerstone that a cancellation proceeding had been initiated by Bausch & Lomb Incorporated, or Bausch & Lomb, against the ALLERX trademark registration. The petition to cancel filed in this proceeding alleges that the ALLERX registration dilutes the distinctive quality of Bausch & Lomb s Alrex® trademark and that Bausch & Lomb is likely to be damaged by the ALLERX registration. Cornerstone is currently engaged in settlement discussions with Bausch & Lomb concerning a refinement of the product description in the ALLERX trademark registration to distinguish it from the product marketed by Bausch & Lomb under the Alrex trademark. Cornerstone responded to the Trademark Trial and Appeal Board on June 24, 2008, opposing the claims in the Bausch & Lomb cancellation petition, while concurrently continuing to seek settlement of the cancellation proceeding on favorable terms. Cornerstone could take any of numerous courses of action, including continuing to oppose the claims of Bausch & Lomb, undertaking action to cancel Bausch & Lomb s registration of its Alrex® trademark or entering into discovery. A final decision by the Trademark Trial and Appeal Board could take several years.

Table of Contents

## CRITICAL THERAPEUTICS MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of financial condition and results of operations together with the Selected Historical Consolidated Financial Data of Critical Therapeutics section of this proxy statement/prospectus and Critical Therapeutics consolidated financial statements and the related notes included in this proxy statement/prospectus. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Critical Therapeutics actual results could differ materially from those anticipated by the forward-looking statements due to important factors including, but not limited to, those set forth in the Risks Related to Critical Therapeutics section of this proxy statement/prospectus.

### Overview

Critical Therapeutics is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory diseases, as well as other inflammatory diseases linked to the body s inflammatory response. Critical Therapeutics two marketed products are ZYFLO CR, which the FDA approved in May 2007, and ZYFLO, which the FDA approved in 1996, for the prevention and chronic treatment of asthma in adults and children 12 years of age or older. Critical Therapeutics licensed from Abbott exclusive worldwide rights to ZYFLO CR, ZYFLO and other formulations of zileuton for multiple diseases and conditions.

Critical Therapeutics began selling ZYFLO CR in the United States in September 2007 and began selling ZYFLO in the United States in October 2005. In February 2008, Critical Therapeutics stopped the manufacture and supply of ZYFLO to the market. In March 2008, Critical Therapeutics began to experience supply chain issues with batches of ZYFLO CR that could not be released into the commercial supply chain because they did not meet its product release specifications. In September 2008, Critical Therapeutics resumed distribution of ZYFLO to help manage any potential impact to patients of supply chain issues for ZYFLO CR.

In addition, Critical Therapeutics is developing zileuton injection initially for use in emergency room or urgent care centers for patients who suffer acute exacerbations of asthma. In June 2008, Critical Therapeutics announced results from its Phase II clinical trial with zileuton injection in patients with chronic, stable asthma. Critical Therapeutics intends to initiate a process to seek to enter into a collaboration agreement for the future clinical development and commercialization of zileuton injection.

Critical Therapeutics is also developing other product candidates directed towards reducing the potent inflammatory response that it believes is associated with the pathology, morbidity and, in some cases, mortality in many acute and chronic diseases. The inflammatory response occurs following stimuli such as infection or trauma. Critical Therapeutics product candidates target the production and release into the bloodstream of proteins called cytokines that play a fundamental role in the body s inflammatory response.

Critical Therapeutics has been conducting preclinical work in its alpha-7 program. Critical Therapeutics believes the successful development of a small molecule product candidate targeting the alpha-7 receptor could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma and rheumatoid arthritis. Based on preclinical studies, Critical Therapeutics selected lead and backup molecules for evaluation in GLP toxicology studies. Provided the data are supportive and sufficient resources are available, Critical Therapeutics believes that an IND could be filed in 2009. In addition, Critical Therapeutics plans to seek collaborations with other pharmaceutical companies for its alpha-7 program to develop and commercialize possible product candidates in multiple development opportunities that may

exist within this program prior to the initiation of human clinical trials. Critical Therapeutics licensed to SetPoint patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. This license agreement specifically excludes from the licensed field pharmacological modulation of the alpha-7 receptor.

Critical Therapeutics has a collaboration agreement with MedImmune for the development of monoclonal antibodies directed toward an HMGB1, which Critical Therapeutics believes may be an important target for

the development of products to treat diseases mediated by the body s inflammatory response. In addition, Critical Therapeutics has a collaboration agreement with Beckman Coulter for the development of a diagnostic directed toward measuring HMGB1 in the bloodstream.

Until the closing of the proposed merger with Cornerstone, Critical Therapeutics expects to continue its commercial and development activities in accordance with its existing business strategy with an increased focus on managing its cash position. The description of Critical Therapeutics business set forth in this proxy statement/prospectus does not reflect any changes to Critical Therapeutics business that may occur if it consummates the proposed merger with Cornerstone. For instance, the combined company s clinical and preclinical pipeline will include a number of product candidates. The combined company is expected to implement a strategic review of its product development pipeline. Following the strategic review, the combined company may seek to maximize the value of any non-core programs through out-licensing, divestiture or spin-off transactions.

On April 21, 2008, Critical Therapeutics received notification that for the prior 30 consecutive business days the bid price of its common stock on The NASDAQ Global Market had closed below the minimum $1.00 per share required for continued inclusion under NASDAQ Marketplace Rule 4450(a)(5).

On May 16, 2008, Critical Therapeutics received notification that its stockholders equity of $7,126,000, as reported in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 that it filed with the SEC, does not comply with the minimum stockholders equity requirement of $10,000,000 for continued listing on The NASDAQ Global Market pursuant to NASDAQ Marketplace Rule 4450(a)(3).

On June 13, 2008, NASDAQ approved the transfer of the listing of Critical Therapeutics common stock from The NASDAQ Global Market to The NASDAQ Capital Market effective at the opening of business on June 17, 2008. A condition to approval of the transfer of the listing was Critical Therapeutics satisfaction of The NASDAQ Capital Market s continued listing requirements, other than the $1.00 per share minimum bid price requirement. Separately, if Critical Therapeutics meets all of The NASDAQ Capital Market s initial listing requirements, other than the minimum bid price requirement, on October 20, 2008, which is the date that is 180 days following the date Critical Therapeutics received notification from NASDAQ that it failed to comply with the minimum bid price requirement, Critical Therapeutics will have the remainder of an additional 180 calendar day grace period while listed on The NASDAQ Capital Market to regain compliance with NASDAQ s minimum bid price requirement. There can be no assurance that on October 20, 2008 Critical Therapeutics will comply with The NASDAQ Capital Market s initial listing requirements, including The NASDAQ Capital Market s minimum stockholders equity requirement.

On August 13, 2008, Critical Therapeutics received notification from the NASDAQ Listing Qualification Department that, based on its stockholders equity of $1.2 million, as reported in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, and a market value of its common stock as of August 12, 2008 of $13.0 million, Critical Therapeutics does not comply with NASDAQ Marketplace Rule 4310(c)(3), which requires it to have, for continued listing on The NASDAQ Capital Market, a minimum of $2.5 million in stockholders equity or market value of listed securities of $35.0 million or $500,000 of net income from continuing operations for the most recently completed fiscal year or two of the three most recently completed fiscal years. As a result, the Listing Qualifications Staff is reviewing Critical Therapeutics eligibility for continued listing on The NASDAQ Capital Market. To facilitate the review, Critical Therapeutics provided to the Listing Qualifications Staff on September 3, 2008 a definitive plan, based on completing the proposed merger with Cornerstone, to achieve and sustain compliance with all NASDAQ Capital Market listing requirements. If after the conclusion of its review process the Listing Qualifications Staff determines that Critical Therapeutics plan does not adequately address the deficiencies noted, the Staff will provide written notice to Critical Therapeutics that its common stock will be delisted from The NASDAQ Capital Market. In such event, Critical Therapeutics may appeal the Staff s decision to a NASDAQ Listing Qualifications Panel.

**Financial Operations Overview**

On March 13, 2007, Critical Therapeutics entered into an agreement with DEY under which Critical Therapeutics and DEY agreed to jointly promote ZYFLO and ZYFLO CR. Under the co-promotion agreement,

Table of Contents

DEY paid Critical Therapeutics a non-refundable upfront payment of $3.0 million upon signing the co-promotion agreement, a milestone payment of $4.0 million following approval by the FDA of the NDA for ZYFLO CR and a milestone payment of $5.0 million following Critical Therapeutics commercial launch of ZYFLO CR. Critical Therapeutics, in accordance with EITF 02-16, has deferred the $12.0 million in aggregate payments received to date and is amortizing these payments over the term of the agreement. The amortization of the upfront and milestone payments will be offset by the co-promotion fees paid to DEY for promoting ZYFLO and ZYFLO CR. Critical Therapeutics records any co-promotion fees paid to DEY and the amortization of the upfront and milestone payments as sales and marketing expenses. Under the co-promotion agreement, Critical Therapeutics records all quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, up to $1.95 million and pays DEY a commission on quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, in excess of $1.95 million.

At June 30, 2008, Critical Therapeutics had $7.8 million in inventory. Critical Therapeutics expects that its inventory levels in the second half of 2008 will increase as a result of its API purchase commitments in the fourth quarter. Significant differences between Critical Therapeutics current estimates and judgments and future estimated demand for its products and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. These differences could have a material adverse effect on its financial condition and results of operations during the period in which Critical Therapeutics recognizes charges for excess inventory. For example, in the quarter ended June 30, 2008, Critical Therapeutics recorded an inventory reserve with respect to an aggregate of eight batches of ZYFLO CR that were not released into Critical Therapeutics commercial supply chain, consisting of one batch of ZYFLO CR that did not meet Critical Therapeutics product release specifications and an additional seven batches of ZYFLO CR that were on quality assurance hold and that did not complete manufacturing within the NDA-specified manufacturing timelines. In addition, in the quarters ended December 31, 2007 and March 31, 2008, Critical Therapeutics recorded inventory reserves with respect to an aggregate of eight batches of ZYFLO CR that could not be released into Critical Therapeutics commercial supply chain because they did not meet Critical Therapeutics product release specifications. These charges were included in cost of products sold in the statements of operations for these periods. In conjunction with Critical Therapeutics three third-party manufacturers for zileuton API, tablet cores and coating and release, Critical Therapeutics has initiated an investigation to determine the cause of this issue, but the investigation is ongoing and is not yet complete. Critical Therapeutics has incurred and expects to continue to incur significant costs in connection with its investigation. To date, the investigation has not identified a clear source of the issue. In August and September 2008, Critical Therapeutics released and made available for shipment to wholesale distributors an aggregate of six batches of finished ZYFLO CR tablets that met its product release specifications. Critical Therapeutics is currently unable to accurately assess the timing and quantity of future batches of ZYFLO CR, if any, that may be released for commercial supply. If not corrected, the ongoing supply chain difficulties could prevent Critical Therapeutics from supplying any further product to its wholesale distributors. Based on its current level of sales and the release of the six batches of ZYFLO CR in August and September 2008, Critical Therapeutics estimates that wholesale distributors and retail pharmacies will have a sufficient inventory of ZYFLO CR to continue to provide product to patients through the fourth quarter of 2008.

Currently, Critical Therapeutics purchases its API for commercial requirements for ZYFLO CR and ZYFLO from a single source. In addition, Critical Therapeutics currently contracts with single third parties for the manufacture of uncoated ZYFLO CR tablets, for the entire manufacturing of ZYFLO tablets and the coating and packaging of ZYFLO CR tablets. The disruption or termination of the supply of API, a significant increase in the cost of the API from this single source or the disruption or termination of the manufacturing of Critical Therapeutics commercial products could have a material adverse effect on its business, financial position and results of operations.

As it moves forward with its proposed merger with Cornerstone, Critical Therapeutics is continuing to focus on conserving cash resources and has begun to take steps to reduce spending on development programs and personnel. On May 8, 2008, as part of this effort, Critical Therapeutics announced that it had eliminated six positions, or approximately 8% of its workforce. The headcount reductions primarily affect Critical Therapeutics research and

development group. In addition, on June 12, 2008, Critical Therapeutics announced that it eliminated an additional 15 positions, or approximately 23% of its remaining workforce during the

Table of Contents

month of June. The June 2008 headcount reductions primarily affect employees performing sales and development functions. Critical Therapeutics may consider further reductions in headcount in additional areas of its business in the future in order to conserve cash and reduce expenses. The nature, extent and timing of future reductions will be made based on Critical Therapeutics business needs and financial resources.

In connection with the implementation of the May 8, 2008 and June 12, 2008 reductions in its workforce, Critical Therapeutics recorded a charge of approximately $1.2 million of severance benefits in the second quarter of 2008.

On June 25, 2007, Critical Therapeutics entered into a definitive agreement with DEY to jointly promote PERFOROMIST, DEY s product for the treatment of COPD. Under the agreement, DEY granted Critical Therapeutics a right and license or sublicense to promote and detail PERFOROMIST in the United States, together with DEY. In October 2007, Critical Therapeutics announced that it had commercially launched PERFOROMIST with DEY. Under the agreement, DEY pays Critical Therapeutics a commission on retail sales of PERFOROMIST above a specified baseline. On July 2, 2008, Critical Therapeutics provided notice to DEY that Critical Therapeutics had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

In July 2003, Critical Therapeutics entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1. Under this collaboration, MedImmune paid Critical Therapeutics initial fees of $10.0 million in late 2003 and $2.5 million in early 2004. In addition, MedImmune agreed to pay Critical Therapeutics $125,000 in 2007, $1.0 million in 2006, $2.75 million in 2005 and $1.5 million in 2004 for milestone payments and to fund certain research expenses incurred by Critical Therapeutics for the HMGB1 program. The total $17.9 million in initial fees and research funding was recognized over the term of the research portion of the license and collaboration agreement using the proportional performance method.

In January 2007, Critical Therapeutics entered into an exclusive license agreement with SetPoint under which Critical Therapeutics licensed to SetPoint patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. In May 2007, under the agreement with SetPoint, Critical Therapeutics received an initial license fee of $500,000 in cash and SetPoint junior preferred stock valued at $500,000 in connection with SetPoint s first financing. However, under Critical Therapeutics license agreement with The Feinstein Institute, Critical Therapeutics was obligated to pay The Feinstein Institute $100,000 of this cash payment and SetPoint junior preferred stock valued at $100,000. Critical Therapeutics included in revenue under collaboration and license agreements in 2007 the $1.0 million total license fee that it received from SetPoint and included in research and development expenses the payments of $100,000 in cash and SetPoint junior preferred stock valued at $100,000 that it made to The Feinstein Institute. These amounts were recorded in the second quarter of 2007. Under the license agreement, SetPoint also has agreed to pay Critical Therapeutics $1.0 million, excluding a $200,000 payment that Critical Therapeutics would be obligated to pay The Feinstein Institute, upon full regulatory approval of a licensed product by the FDA or a foreign counterpart agency and royalties based on a net sales of licensed products and methods by SetPoint and its affiliates. In March 2008, Critical Therapeutics sold the remaining 400,000 shares of junior preferred stock to two investors, which had participated in SetPoint s first financing, for an aggregate purchase price of $400,000. The purchase price is subject to adjustment if these investors sell or receive consideration for these shares of junior preferred stock pursuant to an acquisition of SetPoint prior to February 1, 2009 at a price per share greater than they paid Critical Therapeutics.

***Going Concern Assumption***

Since its inception, Critical Therapeutics has incurred significant losses each year. Critical Therapeutics had net losses of $37.0 million in the year ended December 31, 2007 and $48.8 million in the year ended December 31, 2006. Critical Therapeutics had net losses of $17.4 million in the six months ended June 30, 2008 and $17.6 million in the

six months ended June 30, 2007. As of June 30, 2008, Critical Therapeutics had an accumulated deficit of approximately $209 million. Critical Therapeutics expects to incur significant losses for the foreseeable future and may never achieve profitability. Although the size and timing of its future operating losses are subject to significant uncertainty, Critical Therapeutics expects its operating losses to

Table of Contents

continue over the next several years as its funds its development programs, market and sell ZYFLO CR and prepare for the potential commercial launch of its product candidates. Based on its current operating plan, Critical Therapeutics believes that its available cash and cash equivalents and anticipated cash received from product sales will be sufficient to fund anticipated levels of operations into the first quarter of 2009. Since its inception, Critical Therapeutics has raised proceeds to fund its operations through public offerings of common stock, private placements of equity securities, revenues from sales of ZYFLO and ZYFLO CR, payments from DEY under its zileuton co-promotion agreement, debt financings, the receipt of interest income, payments from its collaborators, MedImmune and Beckman Coulter, license fees from SetPoint.

***Revenues***

From its inception on July 14, 2000 through the third quarter of 2005, Critical Therapeutics derived all of its revenues from license fees, research and development payments and milestone payments that it has received from its collaboration and license agreements with MedImmune and Beckman Coulter. In the fourth quarter of 2005, Critical Therapeutics began selling, and recognizing revenue from, ZYFLO. In September 2007, Critical Therapeutics began selling, and recognizing revenue from, ZYFLO CR. In 2007, Critical Therapeutics also recorded license revenue from its license agreement with SetPoint. In February 2008, Critical Therapeutics stopped the manufacture and supply of ZYFLO to the market. Critical Therapeutics resumed distribution of ZYFLO in September 2008.

***Cost of Products Sold***

Cost of products sold consists of manufacturing, distribution and other costs related to Critical Therapeutics commercial products, ZYFLO and ZYFLO CR. In addition, it includes royalties to third parties related to ZYFLO and ZYFLO CR and any reserves established for excess or obsolete inventory. Most of Critical Therapeutics manufacturing and distribution costs are paid to third-party manufacturers. However, there are some internal costs included in cost of products sold, including salaries and expenses related to managing Critical Therapeutics supply chain and for certain quality assurance and release testing costs.

***Research and Development Expenses***

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for monitoring and analyzing clinical trials, regulatory costs, including user fees paid to the FDA, milestone payments to third parties, costs related to the development of Critical Therapeutics approved NDA for ZYFLO CR, costs of contract research and manufacturing and the cost of facilities. In addition, research and development expenses have included the cost of Critical Therapeutics medical affairs and medical information functions, which educated physicians on the scientific aspects of Critical Therapeutics commercial products and the approved indications, labeling and the costs of monitoring adverse events. After FDA approval of a product candidate, Critical Therapeutics records manufacturing expenses associated with a product as cost of products sold rather than as research and development expenses. Critical Therapeutics expenses research and development costs and patent related costs as they are incurred. Because of Critical Therapeutics ability to utilize resources across several projects, many of its research and development costs are not tied to any particular project and are allocated among multiple projects. Critical Therapeutics records direct costs on a project-by-project basis. Critical Therapeutics records indirect costs in the aggregate in support of all research and development. Development costs for clinical stage programs such as zileuton injection tend to be higher than earlier stage programs such as Critical Therapeutics HMGB1 and alpha-7 programs due to the costs associated with conducting late stage clinical trials and large-scale manufacturing.

Critical Therapeutics expects that research and development expenses relating to its portfolio will fluctuate depending primarily on the timing and outcomes of clinical trials, related manufacturing initiatives and milestone payments to

third parties and the results of its decisions based on these outcomes. Critical Therapeutics also expects manufacturing expenses for some programs included in research and development expenses to increase if it scales up production of zileuton injection for later stages of clinical development.

Table of Contents

Critical Therapeutics initiated a Phase IV clinical trial in July 2007 related to ZYFLO CR to examine its potential clinical benefits in the current patient treatment setting. In March 2008, Critical Therapeutics discontinued the trial because patient enrollment was significantly slower than it had anticipated. In the first quarter of 2008, Critical Therapeutics accrued $1.1 million related to costs to terminate the clinical trial. These costs are included in research and development expenses for the three months ended March 31, 2008. At June 30, 2008, $768,000 remains in accrued expenses related to these termination costs.

As a result of the FDA s approval of the NDA for ZYFLO CR in May 2007, Critical Therapeutics made milestone payments totaling $3.1 million and accrued at present value an additional $3.5 million related to milestone obligations due on the first and second anniversaries of the FDA s approval. Critical Therapeutics included these milestone payments and accruals in research and development expenses in its results for the second quarter of 2007 and included the accretion of the discount related to the present value of the milestone obligations in interest expense. At June 30, 2008, Critical Therapeutics included $1.9 million related to milestone obligations due on the first anniversary of the FDA s approval in its accounts payable.

As part of the approval of the NDA for ZYFLO CR in May 2007, the FDA required Critical Therapeutics to conduct a pediatric clinical trial of ZYFLO CR as a post-approval commitment and report the results to the FDA by June 2010. Critical Therapeutics has not yet begun this pediatric clinical trial. The actual costs and timing of this clinical trial and associated activities are highly uncertain, subject to risk and will change depending upon the design of the pediatric clinical trial that is implemented. If Critical Therapeutics does not successfully begin and complete this clinical trial in the time required by the FDA, Critical Therapeutics ability to market and sell ZYFLO CR may be hindered, and Critical Therapeutics business may be harmed as a result.

***Sales and Marketing Expenses***

Sales and marketing expenses consist primarily of salaries and other related costs for personnel in sales, marketing, managed care and sales operations functions, as well as other costs related to ZYFLO CR and ZYFLO. Critical Therapeutics also incurred marketing and other costs related to its launch of ZYFLO CR in September 2007. Other costs included in sales and marketing expenses include sales and marketing costs related to Critical Therapeutics co-promotion and marketing agreement, cost of product samples of ZYFLO CR and ZYFLO, promotional materials, market research and sales meetings. Critical Therapeutics expects to continue to incur sales and marketing costs associated with enhancing Critical Therapeutics sales and marketing functions and maintaining Critical Therapeutics increased sales force to support ZYFLO CR. In addition, under its co-promotion agreement with DEY, Critical Therapeutics has deferred the $12.0 million in aggregate upfront and milestone payments that it received in 2007. Critical Therapeutics is amortizing these payments over the term of the agreement. The amortization of the upfront and milestone payments will offset some or all of the co-promotion fees paid to DEY for promoting ZYFLO CR and ZYFLO in future periods under the agreement. Critical Therapeutics records all ZYFLO CR and ZYFLO sales generated by the combined sales force and records any co-promotion fees paid to DEY and the amortization of the upfront and milestone payments in sales and marketing expenses.

***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, accounting, legal, business development, information technology and human resource functions. Other costs included in general and administrative expenses include certain facility and insurance costs, including director and officer liability insurance, as well as professional fees for legal, consulting and accounting services.

**Critical Accounting Policies**

The discussion and analysis of Critical Therapeutics financial condition and results of operations are based on Critical Therapeutics consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial

Table of Contents

statements requires Critical Therapeutics to make estimates and judgments that affect its reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, Critical Therapeutics reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

Critical Therapeutics regards an accounting estimate or assumption underlying Critical Therapeutics financial statements as a critical accounting estimate where:

the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

the impact of the estimates and assumptions on financial condition or operating performance is material.

Critical Therapeutics significant accounting policies are more fully described in the notes to its consolidated financial statements included in this proxy statement/prospectus. Not all of these significant accounting policies, however, fit the definition of critical accounting estimates. Critical Therapeutics has discussed its accounting policies with the audit committee of its board of directors, and believes that its estimates relating to revenue recognition, product returns, inventory, accrued and prepaid expenses, short-term investments, stock-based compensation and income taxes described below fit the definition of critical accounting estimates.

***Revenue Recognition***

*Revenue from Product Sales.* Critical Therapeutics sells ZYFLO CR and ZYFLO primarily to pharmaceutical wholesalers, distributors and pharmacies, which have the right to return purchased product. Critical Therapeutics commercially launched ZYFLO in October 2005 and ZYFLO CR in September 2007. Critical Therapeutics recognizes revenue from product sales in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, or SFAS 48, which requires the amount of future returns to be reasonably estimated. Critical Therapeutics recognizes product sales net of estimated allowances for product returns, estimated rebates in connection with contracts relating to managed care, Medicaid and estimated chargebacks from distributors and prompt payment and other discounts. Calculating these gross-to-net sales adjustments involves estimates and judgments based primarily on sales or invoice data and historical experience.

Prior to the first quarter of 2007, Critical Therapeutics deferred the recognition of revenue on ZYFLO product shipments to wholesale distributors until units were dispensed through patient prescriptions as it was unable to reasonably estimate the amount of future product returns. Units dispensed are not generally subject to return. In the first quarter of 2007, based on its product return experience since it launched ZYFLO in October 2005, Critical Therapeutics began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties, as sufficient history existed to make such estimates. In connection with this change in estimate, Critical Therapeutics recorded an increase in net product sales in 2007 related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. This change in estimate totaled approximately $953,000 and was reported in Critical Therapeutics results for the first quarter of 2007. Critical Therapeutics anticipates that the rate of return for ZYFLO CR will be comparable to the historical rate of return for ZYFLO. As a result, Critical Therapeutics recognizes revenue for sales of ZYFLO CR upon shipment to third parties and records a reserve for potential returns from these third parties based on its product returns experience with ZYFLO and other factors.

*Product Returns.* Consistent with industry practice, Critical Therapeutics offers customers the ability to return products during the six months prior to, and the 12 months after, the product expires. At the time of its commercial launch in October 2005, Critical Therapeutics began shipping ZYFLO with an expiration date of 12 months. Since its

launch of ZYFLO, Critical Therapeutics has extended ZYFLO s expiration date from 12 months to 24 months. In September 2007, Critical Therapeutics launched ZYFLO CR, which currently has an expiration date of 18 months. Critical Therapeutics anticipates that the rate of return for ZYFLO CR will be comparable to the historical rate of return for ZYFLO as the products are substantially similar.

Table of Contents

Critical Therapeutics may adjust its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include Critical Therapeutics estimate of inventory levels of its products in the distribution channel, the shelf life of the product shipped, competitive issues, such as new product entrants, and other known changes in sales trends. Critical Therapeutics evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve accordingly. As a result of this ongoing evaluation, Critical Therapeutics product return reserve for ZYFLO CR was $119,000 as of June 30, 2008. Critical Therapeutics expects to resume supply of ZYFLO in September 2008.

*Prompt Payment Discounts.* Critical Therapeutics offers wholesale distributors a 2% prompt payment discount as an incentive to remit payment within the first 30 days after the date of its invoice. Because its wholesale distributors typically take the prompt payment discount, Critical Therapeutics accrues 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of its original sale to them, and Critical Therapeutics applies earned discounts at the time of payment. Critical Therapeutics adjusts the accrual quarterly to reflect actual experience. Historically, these adjustments have not been material. Critical Therapeutics does not anticipate that future changes to its estimates will have a material impact on its net revenue.

*Medicaid Rebates.* Critical Therapeutics participates in state Medicaid programs. Critical Therapeutics records an accrual for rebates to be provided through the Medicaid Drug Rebate Program as a reduction of sales when the product is sold. Critical Therapeutics rebates individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is derived from its Average Manufacturer Price. By statute, states are required to report quarterly drug utilization data to labelers participating in the Medicare or Medicaid rebate program after each reporting period. Critical Therapeutics determines its estimate of the Medicaid rebates accrual primarily based on historical experience regarding Medicaid rebates, legal interpretations of the applicable laws related to the Medicaid program and any new information regarding changes in the Medicaid programs regulations and guidelines that would impact the amount of the rebates. Critical Therapeutics adjusts the accrual rate quarterly to reflect actual experience. Critical Therapeutics does not anticipate that future changes to its estimates will have a material impact on its net revenue.

*Chargebacks.* Although Critical Therapeutics sells ZYFLO and ZYFLO CR primarily to wholesale distributors, as a result of participating in the Medicaid Drug Rebate Program, certain governmental entities, such as the Department of Veterans Affairs or Department of Defense, can purchase product from its wholesalers at a specified discounted price. Critical Therapeutics provides a credit to the wholesale distributor, or a chargeback, representing the difference between the wholesale distributor s acquisition list price and the discounted price. As a result, at the time Critical Therapeutics ships the product and records the related sale, Critical Therapeutics must estimate the likelihood that its products sold to wholesale distributors might ultimately be sold to federal government entities. Critical Therapeutics determines its estimates based on the historical chargeback data Critical Therapeutics receives from wholesalers, which detail historical buying patterns and the applicable chargeback rates. Critical Therapeutics adjusts the accrual rate quarterly to reflect actual experience. Critical Therapeutics does not anticipate that future changes to its estimates will have a material impact on its net revenue.

Table of Contents

The following table provides a summary of activity with respect to Critical Therapeutics sales allowances.

| | Sales Returns | Prompt Payment Discounts | Medicaid Discounts | Chargebacks |
|---|---|---|---|---|
| Balance at January 1, 2005 | $ | $ | $ | $ |
| Current provision | | 54 | 38 | |
| Payments and credits | | (33) | | |
| Balance at December 31, 2005 | | 21 | 38 | |
| Current provision | | 148 | 153 | 91 |
| Changes in prior year estimate | | | (27) | |
| Payments and credits | | (153) | (87) | (81) |
| Balance at December 31, 2006 | | 16 | 77 | 10 |
| Current provision | 1,411 | 238 | 263 | 131 |
| Changes in prior year estimate | | | 17 | |
| Payments and credits | (538) | (229) | (262) | (128) |
| Balance at December 31, 2007 | 873 | 25 | 95 | 13 |
| Current provision | 4 | 141 | 99 | 49 |
| Changes in prior year estimate | (440) | | (18) | 5 |
| Payments and credits | (318) | (136) | (134) | (59) |
| Balance at June 30, 2008 | $ 119 | $ 30 | $ 42 | $ 8 |

*Revenue under Collaboration and License Agreements.* Under its collaboration agreements with MedImmune and Beckman Coulter, Critical Therapeutics is entitled to receive non-refundable license fees, milestone payments and other research and development payments. Payments received are initially deferred from revenue and subsequently recognized in Critical Therapeutics statements of operations when earned. Critical Therapeutics must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by its collaborators. Critical Therapeutics recognizes revenues under its collaboration agreements over the estimated performance period as set forth in the contracts based on proportional performance adjusted from time to time for any delays or acceleration in the development of the product. Critical Therapeutics assesses proportional performance based on the progress of its research and development efforts, including employees salaries and benefits, laboratory supplies and third-party research consulting fees, during the term of its agreements. Critical Therapeutics considers these to be the most reliable measure of progress. Because MedImmune and Beckman Coulter can each cancel its agreement with it, Critical Therapeutics does not recognize revenues in excess of cumulative cash collections. It is difficult to estimate the impact of the adjustments on the results of Critical Therapeutics operations because, in each case, the adjustment is limited to the cash received. In estimating the progress of its research and development activities for the research portion of the MedImmune agreement, Critical Therapeutics utilized assumptions regarding the major drivers of the program, including the proposed duration of the research term, the estimated time to complete the research phase of the program and the expected costs of personnel, laboratory supplies and third-party consulting required to complete its obligations under the research plan. As a result of a change in estimate of the term during which services would be provided from 41 months to 47 months covered by its research plan with MedImmune, Critical Therapeutics decreased revenue

recognized of approximately $237,000 in 2005. In addition, in 2006, Critical Therapeutics revised its estimate of remaining total research and development costs to be incurred under the collaboration agreement with MedImmune as a result of lower than expected research and development costs incurred due to more rapid advancement of the program. This change in estimate resulted in an increase in revenue recognized of approximately $2.0 million in 2006. All of Critical Therapeutics research activities under the research plan with MedImmune were completed in 2007. Critical Therapeutics had no changes in estimates related to its agreement with Beckman Coulter.

Table of Contents

Under its agreement with MedImmune, Critical Therapeutics may receive, subject to the terms and conditions of the agreement, other payments upon the achievement of development and commercialization milestones by MedImmune up to a maximum of $124.0 million, after taking into account payments that Critical Therapeutics is obligated to make to The Feinstein Institute. Critical Therapeutics has not recorded and will not record these future development and commercialization milestones until they are achieved.

Under its license agreement with SetPoint, Critical Therapeutics included in revenue from collaboration and license agreements in the second quarter of 2007 a $1.0 million initial license fee that it received from SetPoint and included in research and development expenses a related $100,000 cash payment and SetPoint preferred stock payment valued at $100,000 that it made to The Feinstein Institute.

***Inventory***

Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out, or FIFO, method. Critical Therapeutics estimate of the net realizable value of its inventories is subject to judgment and estimation. The actual net realizable value of Critical Therapeutics inventories could vary significantly from its estimates and could have a material effect on Critical Therapeutics financial condition and results of operations in any reporting period. Critical Therapeutics determines the estimated useful life of its inventory based upon stability data of the underlying product stored at different temperatures or in different environments. As of June 30, 2008, inventory consists of API, which is raw material in powder form, work-in-process and finished tablets to be used for commercial sale. On a quarterly basis, Critical Therapeutics analyzes its inventory levels and writes down inventory that has become obsolete, inventory that has a cost basis in excess of Critical Therapeutics expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. At June 30, 2008, Critical Therapeutics had an inventory reserve of $2.5 million. The inventory reserve includes $571,000 recorded in the fourth quarter of 2007, $622,000 recorded in the first quarter of 2008, $160,000 recorded in the second quarter of 2008 relating to nine batches that did not meet Critical Therapeutics product release specifications for ZYFLO CR and $1.1 million recorded in the second quarter of 2008 relating to seven additional batches of the tablet cores of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. As of June 30, 2008, Critical Therapeutics had $7.8 million in inventory, net of the inventory reserve. Critical Therapeutics expects its inventory levels to increase in the second half of 2008 as a result of its API purchase commitments in the fourth quarter of 2008.

***Accrued Expenses***

As part of the process of preparing Critical Therapeutics consolidated financial statements, Critical Therapeutics is required to estimate certain expenses. This process involves identifying services that have been performed on Critical Therapeutics behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in Critical Therapeutics consolidated financial statements. Examples of estimated expenses for which Critical Therapeutics accrues include professional service fees, such as fees paid to lawyers and accountants, rebates to third parties, including government programs such as Medicaid or private insurers, contract service fees, such as amounts paid to clinical monitors, data management organizations and investigators in connection with clinical trials, fees paid to contract manufacturers in connection with the production of clinical materials, license fees in connection with the achievement of milestones and restructuring charges.

In connection with rebates, Critical Therapeutics estimates are based on its estimated mix of sales to various third-party payors, which are either contractually or statutorily entitled to certain discounts off Critical Therapeutics listed price of ZYFLO and ZYFLO CR. In the event that Critical Therapeutics sales mix to certain third-party payors is different from its estimates, Critical Therapeutics may be required to pay higher or lower total rebates than it has

estimated. In connection with service fees, Critical Therapeutics estimates are most affected by its understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of Critical Therapeutics service providers invoice it monthly in arrears for services performed; however, certain service providers invoice it based upon milestones in its agreements with them. In the event that it does not identify certain costs that it has begun to

Table of Contents

incur, or, under or over-estimates the level of services performed or the costs of such services, Critical Therapeutics reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often subject to judgment. Critical Therapeutics makes these judgments based upon the facts and circumstances known to it in accordance with generally accepted accounting principles.

***Investments***

Investments consist primarily of U.S. government treasury and agency notes, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, each of investment-grade quality, which have an original maturity date greater than 90 days. These investments are recorded at fair value and accounted for as available-for-sale securities. Critical Therapeutics records any unrealized gain (loss) during the year as an adjustment to stockholders equity unless it determines that the unrealized gain (loss) is not temporary. Critical Therapeutics adjusts the original cost of debt securities for amortization of premiums and accretion of discounts to maturity. Because Critical Therapeutics has determined that the unrealized gain (loss) on its investments has been temporary, it has not recorded any impairment losses since inception.

It is Critical Therapeutics intent to hold its investments until such time as it intends to use them to meet the ongoing liquidity needs of its operations. However, if the circumstances regarding an investment, such as a change in an investment s external credit rating, or its liquidity needs were to change, Critical Therapeutics would consider a sale of the related security prior to the maturity of the underlying investment to minimize any losses. At June 30, 2008, Critical Therapeutics held $284,000 in an auction rate security. In the first and second quarters of 2008, Critical Therapeutics was informed that there was insufficient demand at auction for this security. As a result, this amount is currently not liquid and may not become liquid unless the issuer is able to refinance it. Critical Therapeutics has classified its investment in an auction rate security as a long-term investment and has included the amount in other assets on its balance sheet.

***Stock-Based Compensation***

Critical Therapeutics applies the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123(R), using the modified prospective application method, which requires it to recognize compensation cost for granted, but unvested awards (upon adoption), new awards and awards modified, repurchased, or cancelled after adoption under the fair value method.

Critical Therapeutics accounts for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS 123(R). Critical Therapeutics uses the Black-Scholes option-pricing model to calculate the fair value of stock-based compensation under SFAS 123(R). There are a number of assumptions used to calculate the fair value of stock options or restricted stock issued to employees under this pricing model.

The two factors that most affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of such fair value. Accounting for equity instruments granted by Critical Therapeutics under SFAS 123(R) and EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or EITF 96-18, requires fair value estimates of the equity instrument granted. If Critical Therapeutics estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services can be readily estimated,

Critical Therapeutics uses the value of such goods or services to determine the fair value of the equity instruments. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services cannot be readily estimated, as is true in connection with most stock options and warrants granted to employees or non-employees, Critical Therapeutics estimates the fair value of the equity instruments based upon the

Table of Contents

consideration of factors that it deems to be relevant at the time using cost, market or income approaches to such valuations.

***Income Taxes***

As part of the process of preparing its consolidated financial statements, Critical Therapeutics is required to estimate its income taxes in each of the jurisdictions in which it operates. This process involves estimating Critical Therapeutics actual current tax exposure together with assessing temporary differences resulting from differing treatments of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities.

At December 31, 2007, Critical Therapeutics had federal tax net operating loss carryforwards of approximately $163 million, which expire beginning in 2021, and state tax net operating loss carryforwards of approximately $154 million, which expire beginning in 2008. Critical Therapeutics also has research and experimentation credit carryforwards of approximately $1.9 million as of December 31, 2007, which expire beginning in 2021. Critical Therapeutics has recorded a full valuation allowance as an offset against these otherwise recognizable net deferred tax assets due to the uncertainty surrounding the timing of the realization of the tax benefit. In the event that Critical Therapeutics determines in the future that it will be able to realize all or a portion of a net deferred tax benefit, an adjustment to the deferred tax valuation allowance would increase net income or additional paid in capital for deferred tax assets related to stock compensation deductions in the period in which such a determination is made. The Tax Reform Act of 1986 contains provisions that may limit the utilization of net operating loss carryforwards and credits available to be used in any given year in the event of significant changes in ownership interest, as defined therein.

Critical Therapeutics did not recognize any accrued interest and penalties related to unrecognized tax benefits, as no amounts would be due as a result of its net tax loss carryforward. Critical Therapeutics policy is to record interest and penalties related to unrecognized tax benefits in income tax expense. Tax years for 2000 to 2007 remain subject to examination for federal and numerous state jurisdictions. The primary state tax jurisdiction to which Critical Therapeutics is subject is the Commonwealth of Massachusetts.

**Results of Operations**

***Six Months Ended June 30, 2008 and 2007***

*Revenues*

*Revenue from Product Sales.* Critical Therapeutics recognized revenue from product sales of ZYFLO CR and ZYFLO of $7.2 million in the six months ended June 30, 2008, compared to revenue from product sales of ZYFLO of $5.2 in the six months ended June 30, 2007. The increase in product revenue is primarily attributable to a 66% increase in prescription volume over the corresponding period in 2007, an 11% increase in the wholesale acquisition price of products sold from the corresponding period in 2007 and a $884,000 reduction in Critical Therapeutics product return expense for ZYFLO CR and ZYFLO from the corresponding period in 2007. In addition, in the six months ended June 30, 2007, Critical Therapeutics recorded a $953,000 increase in product sales related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. On January 1, 2007, based on Critical Therapeutics product return experience since the launch of ZYFLO in October 2005, Critical Therapeutics began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties, as Critical Therapeutics was now able to estimate product returns.

*Revenue under Collaboration and License Agreements.* Critical Therapeutics did not recognize any collaboration or license revenue in the six months ended June 30, 2008, compared to $1.7 million recognized in collaboration and

license revenue in the six months ended June 30, 2007. Collaboration revenue in the six months ended June 30, 2007 was primarily due to $737,000 in collaboration revenue from Critical Therapeutics collaboration with MedImmune and $1.0 million in license revenue related to Critical Therapeutics license agreement with SetPoint. Collaboration revenue of $737,000 related to the collaboration

Table of Contents

with MedImmune and Beckman Coulter in the six months ended June 30, 2007 was primarily attributable to the recognition of $400,000 of deferred revenue recognized under Critical Therapeutics collaboration agreement with Beckman Coulter for a license fee paid to develop a diagnostic assay in connection with Critical Therapeutics HMGB1 program. Collaboration revenue in the six months ended June 30, 2007 also included approximately $337,000 related to a portion of the $12.5 million of initial fees MedImmune paid to Critical Therapeutics that Critical Therapeutics recognized over the duration of the contract and the $5.3 million cumulatively billed to MedImmune for milestone payments and development support from the inception of the agreement through March 31, 2007. At June 30, 2008, Critical Therapeutics had no deferred collaboration revenue and had completed the research term of its agreement with MedImmune. Critical Therapeutics revenue recognized from existing collaborations for the remainder of 2008 is likely to decline substantially compared to corresponding periods in 2007 because Critical Therapeutics has now recognized all of the revenue that it previously deferred. Going forward, Critical Therapeutics revenue from collaboration agreements will fluctuate each quarter and will be highly dependent upon the achievement of milestones under its existing agreements, or will be dependent upon entering into new collaboration agreements.

*Costs and Expenses*

*Cost of Products Sold.* Cost of products sold was $4.7 million in the six months ended June 30, 2008, compared to $1.4 million in the six months ended June 30, 2007, an increase of $3.2 million, or 228%. Gross margin was 36% for the six months ended June 30, 2008 and 73% for the six months ended June 30, 2007.

Cost of products sold in the six months ended June 30, 2008 consisted primarily of the expenses associated with manufacturing ZYFLO CR and distributing ZYFLO and ZYFLO CR, royalties to Abbott and Jagotec related to ZYFLO and ZYFLO CR and reserves established for excess or obsolete inventory. Cost of products sold in the six months ended June 30, 2007 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO. As a result of Critical Therapeutics change in estimates relating to recognition of ZYFLO sales, Critical Therapeutics recorded an additional $166,000 in cost of products sold in the six months ended June 30, 2007.

Critical Therapeutics recorded inventory reserves of $1.9 million for the six months ended June 30, 2008. The write-offs in the six months ended June 30, 2008 resulted from five batches of ZYFLO CR that did not meet Critical Therapeutics product release specifications and seven additional batches of the tablet cores of ZYFLO CR that were on quality assurance hold and that did not complete manufacturing within the NDA-specified manufacturing timelines. Critical Therapeutics did not record any inventory reserves during the six months ended June 30, 2007. As a result of the commercial launch of ZYFLO CR in September 2007, Critical Therapeutics gross margins, excluding write-offs, will likely decrease further as a result of an increase in cost of products sold related to ZYFLO CR due to the more complex manufacturing process and supply chain for ZYFLO CR and additional royalty obligations to Abbott and to Jagotec for utilization of its controlled-release technology. This likely decrease could be offset, in part, by an increase in Critical Therapeutics wholesale acquisition price of ZYFLO CR and Critical Therapeutics ability to spread some of its fixed costs associated with managing its supply chain over a larger revenue base in 2008.

*Research and Development Expenses.* Research and development expenses in the six months ended June 30, 2008 were $6.9 million, compared to $13.0 million in the six months ended June 30, 2007, a decrease of approximately $6.1 million, or 47%. This decrease was primarily due to lower expenses associated with Critical Therapeutics ZYFLO CR milestone fees paid and accrued for, its Phase IV clinical trial and its alpha-7 and HMGB1 preclinical programs. These lower expenses were offset, in part, by an increase in expenses related to Critical Therapeutics zileuton injection Phase II clinical trial costs.

Table of Contents

The following table summarizes the primary components of Critical Therapeutics research and development expenses for the six months ended June 30, 2008 and 2007:

| | Six Months Ended June 30, | |
|---|---|---|
| | 2008 | 2007 |
| | (In thousands) | |
| Zileuton (ZYFLO and ZYFLO CR) | $ 3,539 | $ 9,872 |
| Zileuton injection | 1,441 | 315 |
| CTI-01 | | (83) |
| Alpha-7 | 1,046 | 1,847 |
| HMGB1 | 3 | 210 |
| General research and development expenses | 408 | 322 |
| Stock-based compensation expense | 490 | 539 |
| Total research and development expenses | $ 6,927 | $ 13,022 |

The following summarizes the expenses associated with Critical Therapeutics primary research and development programs:

*Zileuton (ZYFLO and ZYFLO CR).* During the six months ended June 30, 2008, Critical Therapeutics incurred $3.5 million in expenses related to its orally-dosed zileuton programs, including ZYFLO and ZYFLO CR, compared to $9.9 million during the six months ended June 30, 2007, a decrease of $6.3 million, or 64%. This decrease was primarily due to the following:

$3.1 million in milestone fees paid to third parties as a result of the FDA s approval of the NDA for ZYFLO CR in May 2007;

$3.5 million in accrued milestone payments to third parties as a result of the FDA s approval of the NDA for ZYFLO CR in May 2007, which are due on the first and second anniversaries of the FDA s approval;

$902,000 reduction in salaries and other personnel related costs as a result of Critical Therapeutics December 2006 and May 2007 restructurings and a reduction in associated facilities and overhead costs;

$426,000 decrease in manufacturing costs related to Critical Therapeutics R(+) isomer program for zileuton; and

$102,000 reduction in clinical and manufacturing costs for ZYFLO.

The decreases in the costs described above were partially offset by a $1.3 million increase in clinical and manufacturing costs related to Critical Therapeutics Phase IV clinical trial for ZYFLO CR, which was discontinued in March 2008, and a $393,000 asset impairment charge related to Critical Therapeutics second supplier program for ZYFLO CR. Critical Therapeutics does not expect to continue to incur substantial research and development expenses for the remainder of 2008 in support of ZYFLO CR.

*Zileuton Injection.* During the six months ended June 30, 2008, Critical Therapeutics incurred $1.4 million in expenses related to its zileuton injection program, compared to $315,000 during the six months ended June 30, 2007, an increase of $1.1 million, or 357%. This increase was primarily due to clinical trial expenses related to Critical Therapeutics Phase II clinical trial for zileuton injection, which began in October 2007. As Critical Therapeutics has completed the analysis of the data and reported the results of the Phase II clinical trial, it does not expect to incur additional costs associated with the development of zileuton injection during the remainder of 2008. Critical Therapeutics currently expects to seek a collaborator to develop and commercialize its zileuton injection product candidate.

Table of Contents

*CTI-01.* During the six months ended June 30, 2008, Critical Therapeutics did not incur any costs related to its CTI-01 program. During the six months ended June 30, 2007, Critical Therapeutics received a net credit of $83,000 related to its CTI-01 program clinical trial costs. Effective February 2007, Critical Therapeutics terminated its license agreements with the University of Pittsburgh and Xanthus Pharmaceuticals Inc. related to the development of CTI-01. Critical Therapeutics does not plan to pursue further development of CTI-01 or to incur additional costs related to CTI-01.

*Alpha-7.* During the six months ended June 30, 2008, Critical Therapeutics incurred $1.0 million in expenses related to its alpha-7 program, compared to $1.8 million during the six months ended June 30, 2007, a 43% decrease. This decrease was primarily due to a reduction in the number of employees working on the program and a reduction in associated facilities and overhead costs. Critical Therapeutics anticipates that the research and development expenses for its alpha-7 program will not grow substantially for the remainder of 2008, as it expects increased costs related to preclinical studies conducted by third parties to advance the lead molecule to be offset by a reduced number of employees working on this program. Critical Therapeutics anticipates that significant additional expenditures will be required to advance any product candidate through preclinical and clinical development. Critical Therapeutics currently expects to seek a collaborator for its alpha-7 program to develop and commercialize possible product candidates. However, because this project is at a very early stage of development, the actual costs and timing of research, preclinical development, clinical trials and associated activities are highly uncertain, subject to risk, and will change depending upon the product candidate Critical Therapeutics chooses to develop, the clinical indications developed, the development strategy adopted, and the terms of a collaboration, if it is able to enter into one. As a result, Critical Therapeutics is unable to estimate the costs or the timing of advancing a small molecule from its alpha-7 program through clinical development.

*HMGB1.* During the six months ended June 30, 2008, Critical Therapeutics incurred $3,000 in expenses related to its HMGB1 program, compared to $210,000 during the six months ended June 30, 2007, a decrease of $207,000, or 99%. Since the end of the second quarter of 2007, Critical Therapeutics has not conducted, and currently does not anticipate conducting in the future, any research and development activities relating to the HMGB1 program. In addition, all of the research and development expenses of the HMGB1 program will be assumed by MedImmune as the program advances into later stages of preclinical development. The expenses for the HMGB1 program previously borne by Critical Therapeutics are reflected in the accompanying statements of operations as part of research and development expenses, while any funding received from MedImmune and Beckman Coulter to support Critical Therapeutics previous research efforts is included in revenue under collaboration agreements.

Critical Therapeutics general research and development expenses, which are not allocated to any specific program, were $408,000 in the six months ended June 30, 2008, compared to $322,000 in the six months ended June 30, 2007, an increase of $86,000, or 27%. Critical Therapeutics general research and development expenses, which are incurred in support of all of its research and development programs, are not easily allocable to any individual program and, therefore, have been included in general research and development expenses.

In addition, Critical Therapeutics stock-based compensation expense was $490,000 in the six months ended June 30, 2008, compared to $539,000 in the six months ended June 30, 2007, a decrease of $49,000, or 9%. This decrease was primarily due to a continued reduction in stock-based compensation expense related to the reduction in the number of consultants and employees performing research and development functions.

*Sales and Marketing.* Sales and marketing expenses for the six months ended June 30, 2008 were $6.0 million, compared to $4.6 million for the six months ended June 30, 2007. The $1.4 million increase was primarily attributable to the following:

$990,000 increase in salary and other costs of employees performing sales and marketing functions;

$1.5 million increase related to promotional materials, advertising and other costs associated with ZYFLO CR that Critical Therapeutics incurred to support its co-promotion agreement with DEY; and

$626,000 increase in co-promotion fees owed to DEY.

Table of Contents

These increases were partially offset by the following:

$626,000 decrease related to amortization of Critical Therapeutics deferred sales and marketing expense;

$830,000 decrease related to expenses to be reimbursed by DEY associated with ZYFLO CR that Critical Therapeutics incurred to support its co-promotion agreement; and

$257,000 decrease in sample costs.

The number of employees performing sales and marketing functions increased to 34 employees at June 30, 2008 from 26 employees at June 30, 2007. Critical Therapeutics expects that its sales and marketing costs will decrease during the remainder of 2008 as it focuses on conserving cash resources and realizes the anticipated benefits of its May and June 2008 restructuring plans.

*General and Administrative Expenses.* General and administrative expenses for the six months ended June 30, 2008 were $6.0 million, compared to $6.6 million for the six months ended June 30, 2007, a decrease of $578,000, or 9%. This decrease was primarily due to a decrease of $905,000 in advisory fees paid in connection with the signing of Critical Therapeutics agreement with DEY in the first quarter of 2007 and a decrease of $411,000 in stock-based compensation expense. These decreases were offset, in part, by an increase of $724,000 in legal fees primarily related to Critical Therapeutics proposed merger with Cornerstone. The number of employees performing general and administrative functions was 12 employees at June 30, 2008 and 14 employees at June 30, 2007. Critical Therapeutics expects that its general and administrative expenses will increase during the remainder of 2008 compared to corresponding periods in 2007 as it incurs additional professional fees relating to the proposed merger with Cornerstone.

*Restructuring Charges.* Restructuring charges totaled $1.2 million in the second quarter of 2008 related to actions Critical Therapeutics took in May and June 2008. In May 2008, Critical Therapeutics announced that it had eliminated six positions, or approximately 8% of its workforce. The headcount reduction primarily affected the research and development group. In addition, in June 2008, Critical Therapeutics announced that it had eliminated an additional 15 positions, or approximately 23% of its remaining workforce. The June 2008 headcount reductions primarily affected employees performing sales and development functions. Critical Therapeutics expects to consider further reductions in its headcount in additional areas of its business in the future in order to conserve cash and reduce expenses. The nature, extent and timing of future reductions will be made based on Critical Therapeutics business needs and financial resources. The restructuring charges for 2008 were comprised of $1.2 million in severance, benefit and other related payments, and $41,000 in vehicle lease termination charges, asset impairment charges and outplacement services.

*Other Income.* Interest income for the six months ended June 30, 2008 was $289,000, compared to $1.2 million for the six months ended June 30, 2007, a decrease of $865,000, or 75%. The decrease was primarily attributable to lower average cash and investment balances and lower interest rates. Interest expense amounted to $85,000 for the six months ended June 30, 2008 and $69,000 for the six months ended June 30, 2007. Interest expense primarily relates to the accretion of the discount on Critical Therapeutics accrued first and second anniversary milestone payments owed to Abbott and Jagotec as a result of the FDA approval of the NDA for ZYFLO CR and borrowings under Critical Therapeutics loan with Silicon Valley Bank for capital expenditures.

***Years Ended December 31, 2007 and 2006***

*Revenues*

*Revenue from Product Sales.* Critical Therapeutics recognized revenue from net product sales related to sales of ZYFLO and ZYFLO CR of $11.0 million in 2007 compared to $6.6 million in 2006, an increase of 66%. The increase in product revenue is primarily attributable to an 11% increase in ZYFLO prescription volume, an 11% increase in ZYFLO s wholesale acquisition price and $2.3 million in net product sales of ZYFLO CR after its launch in September 2007. In addition, in the first quarter of 2007 Critical Therapeutics recorded a

Table of Contents

$953,000 increase in product sales related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns.

*Revenue under Collaboration and License Agreements.* Critical Therapeutics recognized collaboration and license revenues of $1.9 million in 2007 compared to $6.4 million in 2006, a decrease of approximately $4.6 million, or 71%. This decrease was primarily due to a $5.6 million decrease in collaboration revenue from Critical Therapeutics collaborations with MedImmune and Beckman Coulter, offset by $1.0 million in license revenue related to its agreement with SetPoint. Critical Therapeutics did not recognize any license revenue from SetPoint in the year ended December 31, 2006. For 2007, Critical Therapeutics recognized collaboration revenue of $800,000. Critical Therapeutics 2007 collaboration revenue also included:

- $400,000 of previously deferred revenue recognized under its collaboration agreement with Beckman Coulter for a license fee paid to advance into formal product development a diagnostic assay in connection with Critical Therapeutics HMGB1 program;

- approximately $400,000 related to a portion of the $12.5 million of initial fees MedImmune paid to Critical Therapeutics that it recognized over the duration of the agreement with MedImmune; and

- the $5.4 million cumulatively billed to MedImmune for milestone payments and development support from the inception of the agreement with MedImmune through December 31, 2007.

Collaboration revenue for the year ended December 31, 2006 was primarily comprised of the portion of the initial fees MedImmune paid to Critical Therapeutics that it recognized in each period, and the portion of milestone payments and development support billed to MedImmune.

Since it entered into the agreement with MedImmune in 2003, Critical Therapeutics has billed a total of $17.9 million to MedImmune, consisting of the $12.5 million initial payment, a $1.3 million milestone payment and $4.1 million of development support. As of December 31, 2007, Critical Therapeutics has recognized this entire amount as collaboration revenue. At December 31, 2007, Critical Therapeutics had no deferred collaboration revenue and had completed the research term of Critical Therapeutics agreement with MedImmune. Under its agreement with MedImmune, Critical Therapeutics may receive, subject to the terms and conditions of the agreement, other payments upon the achievement of development and commercialization milestones by MedImmune up to a maximum of $124.0 million, after taking into account payments that Critical Therapeutics is obligated to make to The Feinstein Institute. Critical Therapeutics has not recorded and will not record these future development and commercialization milestones until they are achieved. Critical Therapeutics revenue recognized from existing collaborations in 2008 may decline substantially because it has now recognized all of the revenue that it had previously deferred. Going forward, Critical Therapeutics revenue from collaboration agreements will fluctuate each quarter and will be highly dependent upon the achievement of milestones under its existing agreements, or will be dependent upon its entering into new collaboration agreements.

*Costs and Expenses*

*Cost of Products Sold.* Cost of products sold in 2007 was $4.2 million, compared to $2.2 million in 2006. Gross margin was 62% for 2007 and 66% for 2006. Cost of products sold in 2007 consisted of the expenses associated with manufacturing and distributing ZYFLO and ZYFLO CR, royalties to Abbott and Jagotec related to ZYFLO and ZYFLO CR and reserves established for excess or obsolete inventory. As a result of its change in estimates relating to recognition of ZYFLO sales, Critical Therapeutics recorded an additional $166,000 in cost of products sold for 2007. Cost of products sold in 2006 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO. Critical Therapeutics recorded

inventory write-offs of $821,000 for 2007 and $299,000 for 2006. The write-offs in 2007 and 2006 resulted from excess or obsolete inventory that could no longer be used for commercial sale.

*Research and Development Expenses.* Research and development expenses in 2007 were $21.7 million compared to $26.9 million in 2006, a decrease of approximately $5.2 million, or 20%. This decrease was primarily due to lower expenses associated with clinical trials, as well as the reduction in the number of

Table of Contents

employees performing research and development functions following Critical Therapeutics 2006 restructurings, offset, in part, by $6.6 million in milestone payments paid and accrued for during 2007 as a result of the FDA s approval of the NDA for ZYFLO CR in May 2007.

The following table summarizes the primary components of Critical Therapeutics research and development expenses for the years ended December 31, 2007 and 2006:

| | Year Ended December 31, | |
|---|---|---|
| | 2007 | 2006 |
| | (In thousands) | |
| Zileuton (ZYFLO and ZYFLO CR) | $ 14,479 | $ 11,975 |
| Zileuton injection | 1,373 | 2,336 |
| CTI-01 | (77) | 2,960 |
| Alpha-7 | 3,239 | 3,903 |
| HMGB1 | 343 | 1,829 |
| General research and development expenses | 1,275 | 2,600 |
| Stock-based compensation expense | 1,023 | 1,309 |
| Total research and development expenses | $ 21,655 | $ 26,912 |

The following summarizes the expenses associated with Critical Therapeutics primary research and development programs:

*Zileuton (ZYFLO and ZYFLO CR).* During 2007, Critical Therapeutics incurred $14.5 million in expenses related to its orally-dosed zileuton programs, including ZYFLO and ZYFLO CR, compared to $12.0 million during 2006, a 21% increase. This increase was primarily due to the following:

- $3.1 million in milestone fees paid to third parties as a result of the FDA s approval of the NDA for ZYFLO CR in May 2007;
- $3.5 million in accrued milestone payments to third parties as a result of the FDA s approval of the NDA for ZYFLO CR in May 2007, which are due on the first and second year anniversary of the FDA s approval;
- $2.2 million increase in clinical and manufacturing costs related to its Phase IV clinical trial for ZYFLO CR; and
- $863,000 increase in clinical and manufacturing costs related to its R(+) isomer program for zileuton.

The increases in the costs described above were partially offset by the following:

- $2.6 million reduction in clinical and manufacturing costs for ZYFLO and Critical Therapeutics NDA registration batches for ZYFLO CR;
- $1.9 million reduction in milestone fees paid to third parties as a result of the filing of the ZYFLO CR NDA in July 2006;

$1.2 million reduction in operating expenses incurred by its medical affairs and medical information functions, related to its scientific support of ZYFLO, as a result of its 2006 restructurings;

$1.2 million reduction in salaries, other personnel related costs and overhead related to its 2006 restructurings; and

$305,000 reduction in consulting and scientific advisor fees related to the ZYFLO CR NDA registration batches.

Critical Therapeutics anticipates that its research and development expenses related to its ZYFLO CR program for 2008 will consist primarily of costs related to its Phase IV clinical trial for ZYFLO CR, which it discontinued in March 2008.

Table of Contents

*Zileuton Injection.* During 2007, Critical Therapeutics incurred $1.4 million in expenses related to its zileuton injection program, compared to $2.3 million during 2006, a decrease of $963,000, or 41%. This decrease was primarily due to a reduction in clinical trial expenses related to its Phase I/II clinical trial, which concluded in the first half of 2006, offset by costs related to the preparation and initiation of its Phase II clinical trial in October 2007.

*CTI-01.* During 2007, Critical Therapeutics received a net credit of $77,000 related to clinical trial costs associated with its CTI-01 program, compared to expenses of $3.0 million in 2006. The costs incurred in 2006 related primarily to the enrollment and conduct of a Phase II clinical trial of CTI-01 in patients undergoing major cardiac surgery including the use of a cardiopulmonary bypass machine. Effective February 2007, Critical Therapeutics terminated its license agreements with the University of Pittsburgh and Xanthus Pharmaceuticals related to the development of CTI-01.

*Alpha-7.* During 2007, Critical Therapeutics incurred $3.2 million in expenses related to its alpha-7 program, compared to $3.9 million during 2006, a 17% decrease. This decrease was primarily due to a reduction in the number of employees working on the program following Critical Therapeutics October 2006 restructuring.

*HMGB1.* During 2007, Critical Therapeutics incurred $343,000 in expenses related to its HMGB1 program, compared to $1.8 million during 2006, an 81% decrease. This decrease was primarily due to lower license fees, sponsored research and laboratory supplies for Critical Therapeutics continued testing under its collaboration agreement with MedImmune, as well as lower personnel costs devoted to this program.

Critical Therapeutics general research and development expenses, which are not allocated to any specific program, were $1.3 million in 2007 compared to $2.6 million in 2006, a decrease of 51%. This decrease was primarily due to improved methods of allocating Critical Therapeutics research and development overhead expenses to its various programs, including costs related to personnel, laboratory and other facility costs offset, in part, by its impairment of certain laboratory equipment as a result of its abandoning a substantial portion of its current facility. Unallocated facility related costs were $180,000 in 2007, compared to $635,000 in 2006. In addition, unallocated fixed asset impairment and lease abandonment charges were $664,000 in 2007. The remaining general research and development expenses, which are incurred in support of all of Critical Therapeutics research and development programs, are not easily allocable to any individual program, and therefore, have been included in general research and development expenses.

Stock-based compensation expense that related to research and development decreased $286,000 from $1.3 million in 2006 to $1.0 million in 2007. This includes expenses under SFAS 123(R) for employee grants as well as grants made to non-employees who are primarily working on research and development activities. The adjustment to stock-based compensation expense for non-employees is calculated based on the change in fair value of Critical Therapeutics common stock during the period. The decrease in stock-based compensation expense is related primarily to May 2006 and October 2006 reductions in Critical Therapeutics research and development personnel.

*Sales and Marketing Expenses.* Sales and marketing expenses for 2007 were $12.2 million, compared to $18.3 million for 2006. The $6.1 million, or 33%, decrease in 2007 was primarily attributable to the following:

a decrease of approximately $4.3 million in salary and other costs related to the May 2006 and October 2006 reductions in Critical Therapeutics specialty sales force and sales and customer management team;

a decrease of $1.3 million in employee travel and other employee expenses following its personnel reductions in 2006;

a decrease of $903,000 in infrastructure costs to support the sales force, including leased vehicle, computer and software costs;

a decrease of $567,000 related to amortization of its deferred sales and marketing expense;

Table of Contents

a decrease of $302,000 in severance costs and $525,000 of lower stock-based compensation expense related to the departure of its former Senior Vice President of Sales and Marketing in 2006; and

a decrease of $222,000 in stock-based compensation expense primarily related to its employee reductions in 2006.

The decreases were offset, in part, by the following:

an increase of approximately $1.5 million related to promotional materials, advertising and other costs associated with the launch of ZYFLO CR that Critical Therapeutics incurred to support its co-promotion agreement with DEY; and

$680,000 in co-promotion fees paid to DEY in accordance Critical Therapeutics co-promotion agreement.

In May and October 2006, Critical Therapeutics reduced the size of its sales and marketing efforts substantially to bring its cost structure more in-line with the expected future revenue for ZYFLO. In connection with these two restructurings, Critical Therapeutics reduced the size of its sales force promoting ZYFLO from approximately 80 sales representatives at the beginning of 2006 to 18 sales representatives at December 31, 2006. In addition, Critical Therapeutics reduced the size of the sales management team, its customer management, sales operations and marketing functions. In February 2008, Critical Therapeutics ceased manufacturing and supplying ZYFLO. In connection with its launch of ZYFLO CR in September of 2007, Critical Therapeutics increased its sales force from 18 sales representatives at the beginning of 2007 to approximately 41 sales representatives at December 31, 2007.

*General and Administrative Expenses.* General and administrative expenses for 2007 were $13.6 million compared to $13.5 million for 2006. The $116,000, or 1%, increase in 2007 was primarily attributable to the following:

an increase of $1.2 million in advisory fees paid in connection with the upfront and milestones payments that DEY paid Critical Therapeutics in 2007;

an increase of $529,000 in consulting and other expenses primarily related to its review of strategic alternatives;

an increase of $503,000 in legal fees primarily related to its review of strategic alternatives;

an increase of $417,000 related to the additional bonus accrued at December 31, 2007 in accordance with its agreement with its then-current President and Chief Executive Officer;

an increase of $199,000 in audit and accounting related fees primarily related to its 2007 filing on Form S-3, its co-promotion agreement with DEY and its first 401(k) audit; and

an increase of $196,000 in overhead and facility related charges as a result of its facility abandonment that are allocated to general and administrative expenses.

The increases were offset, in part, by the following:

$670,000 of severance costs and $1.3 million of stock-based compensation expense related to the departure of its former President and Chief Executive Officer in June 2006;

$370,000 related to stock-based compensation as a result of its May 2006 and October 2006 restructurings; and

$351,000 in salary and other related costs as a result of the May 2006 and October 2006 employee reductions.

*Restructuring Charges.* Restructuring charges totaled $3.5 million in 2006 related to actions Critical Therapeutics took in May and October 2006. In May 2006, Critical Therapeutics recorded charges of $499,000 for a restructuring of its operations that was intended to better align costs with revenue and operating expectations. In October 2006, Critical Therapeutics announced a second restructuring of its operations to

Table of Contents

focus its resources on the commercialization of ZYFLO CR and on the clinical development of zileuton injection and to significantly reduce its net cash expenditures through lower spending on its existing sales force as well as on its discovery and research programs. The restructuring charges for 2006 were comprised of the following:

- severance, benefit and related payments of approximately $2.1 million;
- asset impairment charges of $501,000 related to computer and laboratory equipment with a net realizable value below its net book value;
- stock-based compensation expense of $622,000 related to the acceleration of vesting of stock options from the departure of Critical Therapeutics former Senior Vice President of Research and Development and Chief Scientific Officer; and
- approximately $335,000 related to the termination of leases on vehicles used by its sales force and outplacement services.

The restructuring charges for 2006 do not include approximately $972,000 of severance expenses and $1.8 million of stock-based compensation related to the departures of Critical Therapeutics former President and Chief Executive Officer and its former Senior Vice President of Sales and Marketing. These amounts have been included in general and administrative expenses and sales and marketing expenses, as described previously. As of December 31, 2007, Critical Therapeutics had completed the implementation of these restructurings and paid all restructuring costs.

*Other*

*Other Income.* Interest income in 2007 was $2.0 million, compared to $2.7 million in 2006. The decrease was primarily attributable to a lower average cash and investment balance during 2007. Interest expense amounted to $209,000 in 2007 and $214,000 in 2006. The interest expense relates to borrowings under Critical Therapeutics loan with Silicon Valley Bank for capital expenditures and the accretion of the discount on its accrued first and second anniversary milestone payments owed to Abbott and Jagotec as a result of the FDA approval of the NDA for ZYFLO CR.

***Years Ended December 31, 2006 and 2005***

*Revenues*

*Revenue from Product Sales.* Critical Therapeutics recognized revenue from product sales related to sales of ZYFLO of $6.6 million in 2006 compared to $387,000 in 2005. Product sales in 2005 reflect the period from launch in October through the end of the year. Under SFAS 48, Critical Therapeutics recognizes revenue from product shipments when it has determined the right to return the product has lapsed or when it can reasonably estimate returns relating to the shipments to third parties. In accordance with SFAS 48, in 2005 and 2006, Critical Therapeutics deferred recognition of revenue on product shipments of ZYFLO to wholesalers, distributors and pharmacies until the product was dispensed through patient prescriptions. Shipments of ZYFLO to third parties that had not been recognized as revenue totaled $1.2 million as of December 31, 2006 and $1.7 million as of December 31, 2005 and were included in deferred product revenue on Critical Therapeutics balance sheet. Critical Therapeutics deferred the cost of product shipped to third parties that had not been recognized as revenue in accordance with its revenue recognition policy until the product was dispensed through patient prescriptions. This deferred cost of products sold totaled $167,000 as of December 31, 2006, compared to $266,000 as of December 31, 2005, and was included in prepaid expenses and other current assets on Critical Therapeutics balance sheet.

*Revenue under Collaboration Agreements.* Critical Therapeutics recognized collaboration revenues of $6.4 million in 2006 compared to $5.8 million in 2005. These revenues were primarily due to the portion of the $12.5 million of initial fees MedImmune paid Critical Therapeutics that Critical Therapeutics recognized in each period, and the $5.25 million cumulatively billed to MedImmune for milestone payments and development support from the inception of the agreement through December 31, 2006.

Table of Contents

Through December 31, 2006, Critical Therapeutics billed a total of $17.9 million under its agreement with MedImmune, consisting of the $12.5 million initial payment, a $1.3 million milestone payment and $4.1 million of development support. Critical Therapeutics recognized $17.5 million of these amounts as collaboration revenue through December 31, 2006. Critical Therapeutics reported the balance of the payments, totaling $275,000, as deferred collaboration revenue and recognized such amount over the remaining estimated research term of its agreement with MedImmune based on the proportion of cumulative costs incurred as a percentage of the total costs estimated for the performance period. In 2006, Critical Therapeutics revised its cost estimate to reflect lower than expected costs to be incurred over the remainder of the contract with MedImmune. The change in estimate resulted in an increase in revenue recognized of approximately $2.0 million in 2006. Critical Therapeutics recognized the balance in deferred revenue during 2007. As of December 31, 2006, Critical Therapeutics also had $400,000 in deferred collaboration revenue under its collaboration agreement with Beckman Coulter, which it recognized as collaboration revenue in the first quarter of 2007.

*Costs and Expenses*

Effective January 1, 2006, Critical Therapeutics adopted the fair value recognition provisions of SFAS 123(R), using the modified prospective method, which allows it to recognize compensation cost for shares granted, but unvested, stock awards, new stock awards and stock awards modified, repurchased, or cancelled after January 1, 2006. The discussion below is impacted by the fact that 2005 amounts do not include the impact of SFAS 123(R).

*Cost of Products Sold.* Cost of products sold in 2006 was $2.2 million, compared to $514,000 in 2005. Cost of products sold consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO. Cost of products sold included charges for inventory write-offs of $299,000 during 2006, compared to $280,000 during 2005. The write-offs resulted from excess or obsolete inventory that no longer can be used for commercial sale.

*Research and Development Expenses.* Research and development expenses in 2006 were $26.9 million compared to $30.0 million in 2005, a decrease of approximately $3.0 million, or 10%. This decrease was primarily due to lower expenses associated with the technology transfer and manufacturing activities associated with ZYFLO and ZYFLO CR, as well as the reduction in the number of employees performing research and development functions following Critical Therapeutics May and October 2006 restructurings. With the commercial launch of ZYFLO in October 2005, the costs of manufacturing ZYFLO were included in cost of products sold.

The following table summarizes the primary components of Critical Therapeutics research and development expenses for the years ended December 31, 2006 and 2005:

| | Year Ended December 31, | |
|---|---|---|
| | 2006 | 2005 |
| | (In thousands) | |
| Zileuton (ZYFLO and ZYFLO CR) | $ 11,975 | $ 12,670 |
| Zileuton injection | 2,336 | 1,656 |
| CTI-01 | 2,960 | 3,045 |
| Alpha-7 | 3,903 | 2,434 |
| HMGB1 | 1,829 | 2,030 |
| General research and development expenses | 2,600 | 7,260 |

| | | |
|---|---|---|
| Stock-based compensation expense | 1,309 | 864 |
| Total research and development expenses | $ 26,912 | $ 29,959 |

Table of Contents

The following summarizes the expenses associated with Critical Therapeutics primary research and development programs:

*Zileuton (ZYFLO and ZYFLO CR).* During 2006, Critical Therapeutics incurred $12.0 million in expenses related to its orally-dosed zileuton programs, including ZYFLO and ZYFLO CR, compared to $12.7 million during 2005, a 5% decrease. This decrease was primarily due to the following:

- lower manufacturing costs related to the product registration of ZYFLO, which was approved for commercial sale in September 2005; and
- reduced costs related to clinical trials of zileuton in 2006 compared to 2005, when it conducted a Phase II clinical trial in patients with moderate to severe inflammatory acne.

The decreases were offset, in part, by the following:

- completion of certain clinical trials related to the pharmacokinetic profile of ZYFLO CR in the bloodstream; and
- initiation of the development of Critical Therapeutics R(+) isomer program for zileuton.

*Zileuton Injection.* During 2006, Critical Therapeutics incurred $2.3 million in expenses related to its zileuton injection program, compared to $1.7 million during 2005, a 41% increase. This increase was primarily due to the completion of a Phase I/II clinical trial of zileuton injection in 60 patients during 2006 as well as the costs to manufacture and supply the drug in support of that clinical trial. During 2005, Critical Therapeutics zileuton injection program was still in a preclinical stage of development

*CTI-01.* During 2006, Critical Therapeutics incurred $3.0 million in expenses related to its CTI-01 program, which was comparable to the expenses incurred in 2005. The costs incurred in both 2006 and 2005 related primarily to the enrollment and conduct of a Phase II clinical trial of CTI-01 in patients undergoing major cardiac surgery including the use of a cardiopulmonary bypass machine. This clinical trial was initiated in 2005 and completed during 2006. Effective February 2007, Critical Therapeutics terminated its license agreement with the University of Pittsburgh related to the development of CTI-01 and its license agreement with Xanthus Pharmaceuticals related to the development of CTI-01.

*Alpha-7.* During 2006, Critical Therapeutics incurred $3.9 million in expenses in connection with research and development of its alpha-7 program, compared to $2.4 million during 2005, a 60% increase. The increase was primarily due to an increase in laboratory supplies and improved methods of allocating Critical Therapeutics research and development overhead expenses to its various programs, including the costs related to facilities, such as its laboratory space, and the depreciation expense on its laboratory equipment. In 2005, most of these expenses were included in Critical Therapeutics general research and development expenses. The number of employees working on alpha-7 during 2006, as compared to 2005, was relatively consistent through most of the year leading up to Critical Therapeutics October 2006 restructuring.

*HMGB1.* During 2006, Critical Therapeutics incurred $1.8 million in expenses for its HMGB1 program, compared to $2.0 million during 2005, a 10% decrease. This decrease was primarily due to lower license fees, sponsored research and laboratory supplies for continued testing under Critical Therapeutics collaboration agreement with MedImmune as well as lower personnel costs devoted to this program. The decreased expenses were partially offset by increases related to the allocation of Critical Therapeutics research and development overhead expenses to its various programs. These overhead expenses include the costs related to facilities,

including Critical Therapeutics laboratory space, and the depreciation expense on its laboratory equipment. In 2005, most of these expenses were included in Critical Therapeutics general research and development expenses. In addition, Critical Therapeutics paid a $250,000 milestone payment in 2005 to the licensor of HMGB1 for establishing preclinical proof-of-concept. The collaboration revenue recognized by Critical Therapeutics in 2006 for this program totaled $6.4 million. The expenses for HMGB1 are reflected in the accompanying statements of operations as part of research and development expenses, while the funding received from

MedImmune and Beckman Coulter to fund Critical Therapeutics research efforts is included in revenue under collaboration agreements.

Critical Therapeutics general research and development expenses, which are not allocated to any specific program, were $2.6 million in 2006 compared to $7.3 million in 2005, a decrease of 64%. This decrease was primarily due to improved methods of allocating Critical Therapeutics research and development overhead expenses to its various programs, including costs related to personnel, laboratory and other facility costs. Unallocated facility and related costs were $635,000 in 2006, compared to $1.7 million in 2005. Unallocated depreciation expense declined to $59,000 in 2006, compared to $398,000 in 2005. The remaining general research and development expenses, which are incurred in support of all of Critical Therapeutics research and development programs, are not easily allocable to any individual program, and therefore, have been included in general research and development expenses.

Stock-based compensation expense related to research and development increased by $445,000 from $864,000 in 2005 to $1.3 million in 2006. The 2006 amount includes expenses for employee grants under SFAS 123(R) as well as grants made to non-employees who were primarily working on research and development activities. The adjustment to stock-based compensation expense for non-employees is calculated based on the change in fair value of Critical Therapeutics common stock during the period. The increase in stock-based compensation expense is related primarily to Critical Therapeutics adoption of SFAS 123(R), offset in part by the change in the market price of its common stock for unvested non-employee grants.

*Sales and Marketing Expenses.* Sales and marketing expenses for 2006 were $18.3 million, compared to $13.7 million for 2005. The $4.6 million, or 34%, increase in 2006 was primarily attributable to the following:

an increase of approximately $2.2 million in salary costs related to Critical Therapeutics specialty sales force and its sales and customer management team, the majority of whom it hired in August 2005;

$513,000 of additional stock-based compensation expense primarily related to its adoption of SFAS 123(R) and the increased number of employees during most of 2006;

higher infrastructure costs to support the sales force including leased vehicle, computer and software costs;

severance costs of $302,000 and additional stock-based compensation expense of $525,000 related to the departure of its former Senior Vice President of Sales and Marketing; and

higher product samples, promotional materials and other costs associated with ZYFLO that it incurred to support its sales effort.

In May and October 2006, Critical Therapeutics reduced the size of its sales and marketing efforts substantially to bring its cost structure more in-line with the expected future revenue for ZYFLO. In connection with these two restructurings, Critical Therapeutics reduced the size of its sales force promoting ZYFLO from approximately 80 sales representatives at the beginning of 2006 to 18 sales representatives at December 31, 2006. In addition, Critical Therapeutics reduced the size of the sales management team, its customer management, sales operations and marketing functions for similar reasons.

*General and Administrative Expenses.* General and administrative expenses for 2006 were $13.5 million compared to $11.4 million for 2005. The $2.1 million, or 18%, increase in 2006 was primarily attributable to the following:

severance costs of $670,000 and additional stock-based compensation expense of $1.3 million related to the departure of Critical Therapeutics former President and Chief Executive Officer Dr. Rubin; and

$1.7 million of additional stock-based compensation expense primarily related to its adoption of SFAS 123(R).

These increases were offset, in part, by expenses related to Critical Therapeutics June 2005 private placement, lower personnel costs related to its May and October 2006 restructurings and a reduction in expenses related to its compliance with the Sarbanes-Oxley Act.

Table of Contents

*Restructuring Charges.* Restructuring charges totaled $3.5 million in 2006 related to actions Critical Therapeutics took in May and October 2006. In May 2006, Critical Therapeutics recorded charges of $499,000 for a restructuring of its operations that was intended to better align costs with revenue and operating expectations. In October 2006, Critical Therapeutics announced a second restructuring of its operations to focus its resources on the commercialization of ZYFLO CR and on the clinical development of zileuton injection and to significantly reduce its net cash expenditures through lower spending on its existing sales force as well as on its discovery and research programs. The restructuring charges for 2006 do not include approximately $972,000 of severance expenses and $1.8 million of stock-based compensation related to the departures of Critical Therapeutics President and Chief Executive Officer and its Senior Vice President of Sales and Marketing. These amounts have been included in general and administrative expenses and sales and marketing expenses, as described above. At December 31, 2006, Critical Therapeutics had substantially completed the implementation of these restructurings and approximately $212,000 of accrued restructuring costs remaining on its balance sheet was paid in 2007.

*Other*

*Other Income.* Interest income in 2006 was $2.7 million, compared to $2.4 million in 2005. The increase was primarily attributable to higher interest rates and higher cash and investment balances as a result of the financings that Critical Therapeutics completed in 2005 and 2006. Interest expense amounted to $214,000 in 2006 and $191,000 in 2005. The interest expense relates to borrowings under Critical Therapeutics loan with Silicon Valley Bank for capital expenditures.

**Liquidity and Capital Resources**

***Sources of Liquidity***

Since its inception on July 14, 2000, Critical Therapeutics has raised proceeds to fund its operations through public offerings and private placements of equity securities, debt financings, the receipt of interest income, payments from its collaboration, license and co-promotion agreements, the exercise of stock options, and revenues from sales of ZYFLO and ZYFLO CR. As of June 30, 2008, Critical Therapeutics had $11.2 million in cash, cash equivalents and investments. Critical Therapeutics has invested its cash and cash equivalents primarily in highly liquid, interest-bearing, investment grade securities in accordance with its established corporate investment policy.

In July 2003, Critical Therapeutics entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1, a newly discovered cytokine. Under this collaboration, MedImmune paid Critical Therapeutics initial fees of $12.5 million and an additional $5.4 million through June 30, 2008 for milestone payments and to fund certain research expenses incurred by Critical Therapeutics for the HMGB1 program. As of June 30, 2008, Critical Therapeutics had completed the research portion of its agreement with MedImmune and will not conduct any future research or development activities under this agreement.

Under its collaboration with MedImmune, Critical Therapeutics may receive additional payments upon the achievement of research, development and commercialization milestones up to a maximum of $124.0 million, after taking into account payments it is obligated to make to The Feinstein Institute on milestone payments it receives from MedImmune.

Under its co-promotion agreement with DEY, Critical Therapeutics received a non-refundable upfront payment of $3.0 million in March 2007, a milestone payment of $4.0 million in June 2007 following approval by the FDA of the NDA for ZYFLO CR in May 2007 and a milestone payment of $5.0 million in December 2007 following the commercial launch of ZYFLO CR.

***Cash Flow***

*Operating Activities.* Net cash used in operating activities was $23.2 million for the six months ended June 30, 2008, compared to $8.5 million for the six months ended June 30, 2007, an increase of $14.7 million,

Table of Contents

or 172%. Net cash used in operations for the six months ended June 30, 2008 consisted of a net loss of $17.4 million, depreciation and amortization expense, the amortization of premiums on short-term investments, the loss on the disposal of fixed assets and impairment charge on fixed assets of $601,000, stock-based compensation expense of $1.5 million and a $7.9 million decrease as a result of changes in the working capital accounts. This $7.9 million decrease was primarily due to a $2.2 million increase in inventory, a $1.9 million decrease in accrued license fees and a $2.8 million reduction in its accounts payable and accrued expenses.

*Investing Activities.* Investing activities provided $677,000 of net cash in the six months ended June 30, 2008, compared to $212,000 in the six months ended June 30, 2007. During the six months ended June 30, 2008, Critical Therapeutics made minimal capital expenditures. Net cash provided by investing activities for the six months ended June 30, 2008 primarily related to proceeds from Critical Therapeutics sale of assets of $278,000 and its sale of its SetPoint stock for $400,000. In addition, as interest rates have gradually decreased, Critical Therapeutics has maintained more of its investments as cash equivalents rather than short-term investments.

*Financing Activities.* In the six months ended June 30, 2008, Critical Therapeutics used $370,000 of net cash in financing activities, compared to $261,000 in the six months ended June 30, 2007. Net cash used in financing activities for the six months ended June 30, 2008 primarily related to the repayment of long-term debt.

***Income Taxes***

Critical Therapeutics has accumulated net operating losses and tax credits available to offset future taxable income for federal and state income tax purposes as of June 30, 2008. If not utilized, federal net operating loss carryforwards will begin to expire in 2021. State net operating loss carryforwards began to expire in 2006. The federal tax credits expire beginning in 2021. To date, Critical Therapeutics has not recognized the potential tax benefit of its net operating loss carryforwards or credits on its balance sheet or statements of operations. The future utilization of Critical Therapeutics net operating loss carryforwards may be limited based upon changes in ownership pursuant to regulations promulgated under the Internal Revenue Code.

***Funding Requirements and Going Concern***

Critical Therapeutics has experienced significant operating losses in each year since its inception in 2000. Critical Therapeutics had net losses of $37.0 million in the year ended December 31, 2007 and $48.8 million in the year ended December 31, 2006. Critical Therapeutics had net losses of $17.4 million in the six months ended June 30, 2008 and $17.6 million in the six months ended June 30, 2007. As of June 30, 2008, Critical Therapeutics had an accumulated deficit of approximately $209 million. Critical Therapeutics expects that it will continue to incur substantial losses for the foreseeable future as it spends significant amounts to fund its development and commercialization efforts. As a result, there is substantial doubt about Critical Therapeutics ability to continue as a going concern. Critical Therapeutics ability to continue as a going concern will require it to obtain additional financing to fund its operations. Critical Therapeutics has prepared its financial statements on the assumption that it will continue as a going concern, which contemplates the realization of assets and discharge of liabilities in the normal course of business. Doubt about Critical Therapeutics ability to continue as a going concern may make it more difficult to obtain financing for the continuation of operations and could result in the loss of confidence by investors, creditors, suppliers and employees.

Critical Therapeutics expects to devote substantial resources to support the marketing of ZYFLO CR and to fund the development of its product candidates. Critical Therapeutics has not made, and does not expect to make, a significant investment in capital expenditures in 2008. Critical Therapeutics expects to fund any capital expenditures through cash received from product sales and interest income from invested cash and cash equivalents and short-term investments. Critical Therapeutics funding requirements will depend on numerous factors, including:

the ongoing costs of the sales and marketing of ZYFLO CR;

the amount and timing of sales and returns of ZYFLO CR and ZYFLO;

Table of Contents

- the costs of ongoing manufacturing activities for ZYFLO CR and ZYFLO;
- the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals for Critical Therapeutics other product candidates;
- the timing, receipt and amount of milestone and other payments, if any, from DEY, MedImmune, Beckman Coulter, SetPoint or future collaborators or licensees;
- the timing, receipt and amount of sales and royalties, if any, from Critical Therapeutics product candidates;
- continued progress in Critical Therapeutics research and development programs, as well as the magnitude of these programs, including milestone payments to third parties under Critical Therapeutics license agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the cost of obtaining and maintaining licenses to use patented technologies;
- potential acquisition or in-licensing of other products or technologies;
- Critical Therapeutics ability to establish and maintain additional collaborative or co-promotion arrangements; and
- the ongoing time and costs involved in corporate governance requirements, including work related to compliance with the Sarbanes-Oxley Act.

Other than payments that Critical Therapeutics may receive from its collaborations with MedImmune and Beckman Coulter, sales of ZYFLO CR and ZYFLO represent Critical Therapeutics only sources of cash flows and revenue. In addition to the foregoing factors, Critical Therapeutics believes that its ability to access external funds will depend upon market acceptance of ZYFLO CR, the success of its other preclinical and clinical development programs, the receptivity of the capital markets to financings by biopharmaceutical companies, its ability to enter into additional strategic collaborations with corporate and academic collaborators and the success of such collaborations.

The extent of Critical Therapeutics future capital requirements is difficult to assess and will depend largely on its ability to successfully manufacture and commercialize ZYFLO CR. Based on its operating plans, Critical Therapeutics believes that its available cash and cash equivalents and anticipated cash received from product sales will be sufficient to fund anticipated levels of operations into the first quarter of 2009.

For the six months ended June 30, 2008, Critical Therapeutics net cash used for operating activities was $23.2 million, and Critical Therapeutics had minimal capital expenditures. If Critical Therapeutics existing resources are insufficient to satisfy its liquidity requirements or if Critical Therapeutics acquires or licenses rights to additional product candidates, it may need to raise additional external funds through collaborative arrangements and public or private financings. Under Critical Therapeutics merger agreement with Cornerstone, any financing transaction would require Cornerstone s consent. Additional financing may not be available to Critical Therapeutics on acceptable terms or at all. In addition, the terms of the financing may adversely affect the holdings or the rights of Critical Therapeutics stockholders. For example, if Critical Therapeutics raises additional funds by issuing equity securities, further dilution to Critical Therapeutics then-existing stockholders will result. Such equity securities may have rights and preferences superior to those of the holders of Critical Therapeutics common stock. If Critical Therapeutics is unable to obtain funding on a timely basis, Critical Therapeutics may be required to significantly delay, limit or eliminate one or more

of its development or commercialization programs, which could harm its financial condition and operating results. Critical Therapeutics also could be required to seek funds through arrangements with collaborators or others that may require Critical Therapeutics to relinquish rights to some of its technologies, product candidates or products, which Critical Therapeutics would otherwise pursue on its own.

Table of Contents

***Contractual Obligations***

Critical Therapeutics has summarized in the table below its fixed contractual obligations as of June 30, 2008:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| **Contractual Obligations** | **Total** | **Less Than One Year** | **One to Three Years** | **Three to Five Years** | **More Than Five Years** |
| | | | **(In thousands)** | | |
| Manufacturing and clinical trial agreements | $ 16,002 | $ 9,087 | $ 6,907 | $ 8 | $ |
| Research and license agreements | 10,030 | 3,925 | 825 | 920 | 4,360 |
| Marketing costs | 6,737 | 2,237 | 4,500 | | |
| Severance agreements | 892 | 892 | | | |
| Lease obligations | 277 | 277 | | | |
| Consulting agreement | 36 | 36 | | | |