

CRITICAL THERAPEUTICS INC

Form S-4/A

August 28, 2008

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**As filed with the Securities and Exchange Commission on August 28, 2008**

**Registration No. 333-152442**

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

**AMENDMENT NO. 1  
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**

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

**000-50767**

*(Primary Standard Industrial  
Classification Code Number)*

**04-3523569**

*(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)*

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**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.

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.

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.

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

**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.**

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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 AUGUST 28, 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 \_\_\_\_\_, 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**

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**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 23.**

**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.

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

**NOTICE OF SPECIAL MEETING OF STOCKHOLDERS  
To Be Held On \_\_\_\_\_, 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 \_\_\_\_\_, 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.

\_\_\_\_\_, 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**

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**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.**

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**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 335.

**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.

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<u>Ex-10.54 Form of Letter Agreement for Critical Therapeutics, Inc. "Change of Control" Cash Bonus Program, dated as of July 17, 2008</u>	
<u>Ex-23.1 Consent of Deloitte &amp; Touche LLP, Independent Registered Public Accounting Firm to Critical Therapeutics.</u>	
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**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.

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**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.

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**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 \_\_\_\_\_, 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.

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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](mailto:crtx.info@morrowco.com).

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**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 335 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<sup>®</sup> (zileuton) extended-release tablets, or ZYFLO CR, which the U.S. Food and Drug Administration, or FDA, approved in May 2007, and ZYFLO<sup>®</sup> (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 been collaborating with third parties on 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 six 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 68 of this proxy statement/prospectus and the section entitled "Cornerstone's Business - Regulatory Matters" beginning on page 219 of this proxy statement/prospectus.



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Cornerstone derives revenues from the following products as of July 31, 2008:

<b>Product</b>	<b>Promoted by Cornerstone</b>	<b>Approved by FDA</b>
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:

<b>Product Candidate</b>	<b>Regulatory Status</b>	<b>Therapeutic Class</b>	<b>Development Stage</b>
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

Other Product Candidates			begin in 2009
CBP 058	NDA submission targeted in 2010	Antihistamine and anticholinergic combination	Phase I clinical trial targeted to begin in the fourth quarter of 2008
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

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**Summary of the Merger (see page 94)**

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 106)**

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 112)**

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

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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 134)***

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 135)***

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.

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***No Solicitation (see page 137)***

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 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 144)***

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,



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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 145)***

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 148)**

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 290)**

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:

<b>Name</b>	<b>Position with the Combined Company</b>	<b>Current Position</b>
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 and Chief Financial Officer, effective September 8, 2008

**The Board of Directors Following the Merger (see page 292)**

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 118)**

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.

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

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approximately \$305,000 and accelerated vesting of restricted stock with an aggregate value of approximately \$30,589, assuming that the merger had been consummated on July 31, 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 \$1,757,203, accelerated vesting of restricted stock with an aggregate value of approximately \$60,817 and additional aggregate payments of approximately \$108,150 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 July 31, 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 \$0.30 per share, the closing market price of Critical Therapeutics common stock on July 31, 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.

As of July 31, 2008, all directors and executive officers of Critical Therapeutics, together with their affiliates, beneficially owned approximately 23.1% 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 122)**

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.

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Assuming that the merger had been consummated on July 31, 2008, Cornerstone's executive officers and directors, and their affiliates, would beneficially own, in the aggregate, approximately 50% 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 July 31, 2008. Assuming that the merger had been consummated on July 31, 2008 and assuming an exchange ratio of 2.447466, 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:

<b>Name</b>	<b>Total Shares Beneficially Owned</b>	<b>Total Options Held</b>	<b>Options Exercisable Within 60 Days</b>	<b>Combined Company Beneficial Ownership Percentage</b>
Craig A. Collard	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(1)		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(2)	3,186,052			2.5

- (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 will become 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 July 31, 2008, the outstanding principal amount of the Carolina Note was approximately \$9.0 million, which assuming an exchange ratio of 2.447466 would be converted into approximately

14,439,135 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 125)**

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

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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). To the extent not exercised prior to the consummation of the merger, Cornerstone anticipates that there will be approximately 7,976,588 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 July 31, 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 127)**

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 23)**

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.

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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.

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 127)**

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 131)**

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 131)**

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 322)**

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.



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**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.

	<b>Six Months Ended</b>		<b>Year Ended December 31,</b>				
	<b>June 30,</b>	<b>June 30,</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>
	<b>2008</b>	<b>2007</b>					
	<b>(In thousands, except share and per share data)</b>						
<b>Statements of Operations Data:</b>							
Net product sales	\$ 7,227	\$ 5,185	\$ 11,008	\$ 6,647	\$ 387	\$	\$
Revenue under licensing and co-development agreements		1,737	1,861	6,431	5,837	4,436	1,020
Total revenues	7,227	6,922	12,869	13,078	6,224	4,436	1,020
Cost of products sold	4,657	1,421	4,233	2,222	514		
Research and development	6,927	13,022	21,655	26,912	29,959	25,578	17,450
Selling and marketing	6,031	4,582	12,193	18,284	13,671	1,199	
General and administrative	6,010	6,588	13,572	13,456	11,406	9,679	3,770
Restructuring charges	1,204			3,498			
	24,829	25,613	51,653	64,372	55,550	36,456	21,220

Operating loss	(17,602)	(18,691)	(38,784)	(51,294)	(49,326)	(32,020)	(20,200)
Interest income	289	1,154	2,020	2,726	2,427	1,098	19,000
Interest expense	(85)	(69)	(209)	(214)	(191)	(172)	(9,000)
Net loss			(36,973)	(48,782)	(47,090)	(31,094)	(20,110)
Retirement of dividends							
Additional offering costs on preferred stock						(2,209)	(2,260)
Net loss available to common stockholders	\$ (17,398)	\$ (17,606)	\$ (36,973)	\$ (48,782)	\$ (47,090)	\$ (33,303)	\$ (22,370)
Net loss per common share:							
Basic and diluted	\$ (0.41)	\$ (0.41)	\$ (0.87)	\$ (1.37)	\$ (1.61)	\$ (2.28)	\$ (33.90)
Weighted-average basic and diluted shares outstanding	42,857,558	42,513,852	42,580,884	35,529,048	29,276,243	14,631,371	658,200

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	<b>June 30,</b>			<b>December 31,</b>			
	<b>2008</b>	<b>2007</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>
	<b>(In thousands)</b>						
<b>Balance Sheet Data:</b>							
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-53. 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-86. 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.

	<b>Six Months Ended</b>		<b>Year Ended December 31,</b>			<b>March 30,</b>
	<b>June 30,</b>	<b>June 30,</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<b>2008</b>	<b>2007</b>				<b>(Inception)</b>
						<b>through</b>
						<b>December 31,</b>
						<b>2004</b>
	<b>(In thousands, except share and per share data)</b>					
<b>Statements of Operations Data:</b>						
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



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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

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	<b>June 30,</b>		<b>December 31,</b>			
	<b>2008</b>	<b>2007</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<b>(In thousands)</b>					
<b>Balance Sheet Data:</b>						
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)

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**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 335 of this proxy statement/prospectus for more information.

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	<b>Six Months Ended June 30, 2008</b>	<b>Year Ended December 31, 2007</b>
	<b>(In thousands)</b>	
<b>Unaudited Pro Forma Condensed Combined Statements of Operations Data:</b>		
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	45,150
Restructuring charges	1,204	
Total costs and expenses	45,708	78,695
Other (expense) income	(518)	70
Loss before income taxes	(15,187)	(37,685)
Provision for income taxes	839	130
Net loss	\$ (16,026)	\$ (37,815)

	<b>As of June 30, 2008</b>
	<b>(In thousands)</b>
<b>Unaudited Pro Forma Condensed Combined Balance Sheet Data:</b>	
Cash and cash equivalents	\$ 9,020
Working capital	6,528
Total assets	58,159
Total liabilities	32,652
Total stockholders' equity	25,507

**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-53 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 311 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 310 of this proxy statement/prospectus.

**CRITICAL THERAPEUTICS**

	<b>Year Ended December 31, 2007</b>	<b>Six Months Ended June 30, 2008</b>
<b>Historical Per Common Share Data:</b>		
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**

	<b>Year Ended December 31, 2007</b>	<b>Six Months Ended June 30, 2008</b>
<b>Historical Per Common Share Data:</b>		
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**

	<b>Year Ended December 31, 2007</b>	<b>Six Months Ended June 30, 2008</b>
<b>Combined Unaudited Pro Forma Per Common Share Data:</b>		
Net loss per combined common share from continuing operations, basic and diluted	\$ (0.34)	\$ (0.13)
Book value per combined common share	\$ 0.21	\$ 0.21
<b>Equivalent Pro Forma Per Common Share Data:</b>		
Net loss per combined common share from continuing operations, basic and diluted	\$ (0.96)	\$ (0.33)
Book value per combined common share	\$ 0.60	\$ 0.54

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**

	<b>High</b>	<b>Low</b>
<b>Year Ended December 31, 2006</b>		
First Quarter	\$ 7.41	\$ 4.72
Second Quarter	6.25	3.28
Third Quarter	4.50	2.08
Fourth Quarter	3.28	1.45
<b>Year Ended December 31, 2007</b>		
First Quarter	\$ 2.72	\$ 1.44
Second Quarter	4.10	1.50
Third Quarter	2.54	1.66
Fourth Quarter	2.70	1.20
<b>Year Ended December 31, 2008</b>		
First Quarter	\$ 1.45	\$ 0.67
Second Quarter	0.72	0.26
Third Quarter (through August 28, 2008)	0.42	0.26

On April 30, 2008, the last full trading 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





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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 [redacted], 2008 Critical Therapeutics had approximately [redacted] 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.

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**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 \$30,589, assuming that the merger had been consummated on July 31, 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 \$1,757,203, accelerated vesting of restricted stock with an aggregate value of approximately \$60,817 and additional aggregate payments of approximately \$108,150 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 July 31, 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 \$0.30 per share, the closing market price of Critical Therapeutics common stock on July 31, 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.

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

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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 July 31, 2008, Cornerstone's executive officers and directors, and their affiliates, would beneficially own, in the aggregate, 65,748,480 shares, or approximately 50%, 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 6,406,239 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 July 31, 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 118 and 122, 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 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.

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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 full trading 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 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.



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***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.

***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 57 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 57 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 expects to resume 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

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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 ZYFO 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

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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 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

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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 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<sup>®</sup> (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



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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 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,

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AstraZeneca PLC commercially launched in the United States Symbicort<sup>®</sup>, 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<sup>®</sup> and Serevent<sup>®</sup> and Spiriva<sup>®</sup>, a once-daily muscarinic antagonist from Boehringer Ingelheim 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<sup>®</sup>.

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<sup>®</sup>, Johnson & Johnson's Remicade<sup>®</sup>, Bristol-Myers Squibb Company's Orenicia<sup>®</sup>, Abbott Laboratories' Humira<sup>®</sup> and Rituxan<sup>®</sup> marketed by Biogen Idec Inc. and Genentech, Inc., and diseases such as sepsis, like Eli Lilly and Company's Xigris<sup>®</sup>. 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 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.

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***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 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

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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 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.



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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 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.

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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 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

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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 2008, Critical Therapeutics released and made available for shipment to wholesale distributors five 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 five batches of ZYFLO CR in August 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.

In April 2008, Critical Therapeutics began to reinitiate manufacture of ZYFLO in order to have a supply of ZYFLO available if Critical Therapeutics decides it is necessary to reinitiate marketing and supply of ZYFLO to the market given the supply chain issues being experienced for ZYFLO CR. Critical Therapeutics currently anticipates that it will resume distribution of ZYFLO in September 2008 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 would 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.

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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 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.



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***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 Critical Therapeutics achievement of specific development and commercialization milestones that Critical Therapeutics may not meet. 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. Under the collaboration agreement, Critical Therapeutics is obligated to use commercially reasonable, good faith efforts to conduct the collaboration in accordance with rolling three-year research plans that describe and allocate between MedImmune and Critical Therapeutics responsibility for, among other things, the proposed research, preclinical studies, toxicology formulation activities and clinical studies for that time period. In 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'

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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.

***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

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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 plans to rely on MedImmune for the commercialization of any anti-HMGB1 products that Critical Therapeutics develops, 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.

### **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;

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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 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



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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.

***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

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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.

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.

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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 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.

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**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;

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



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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' 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

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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.

***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 47 employees as of July 31, 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.



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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 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

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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 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.



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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.

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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;

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.

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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 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.



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***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;

finances;

restrictions on importation of Critical Therapeutics product candidates;

injunctions; and

civil and criminal penalties.

***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



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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 full trading 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).

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 expects to provide to the Listing Qualifications Staff on or before September 4, 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.

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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.

***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.

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***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;

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**

***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 July 31, 2008, Critical Therapeutics had approximately \$1.6 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.

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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.

**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<sup>®</sup>, or ALLERX, Dose Pack products, Spectracef<sup>®</sup> (cefditoren pivoxil), or SPECTRACEF, and Balacet<sup>®</sup> 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;

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;



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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 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;

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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 July 31, 2008, this organization included a respiratory-focused sales team made up of 50 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 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

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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.

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 Ceda® (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 Vantif® (cefepodoxime), GlaxoSmithKline plc's Ceftin®

(cefuroxime) and Bristol-Myers Squibb Company's Cefz® (cefprozil); macrolides, such as generic formulations of Pfizer Inc.'s Zithromax® (azithromycin) and Abbott Laboratories, Inc.'s

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Biaxin<sup>®</sup> (clarithromycin); and quinolones, such as Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Levaquin<sup>®</sup> (levofloxacin) and generic formulations of Bayer AG's Cipr<sup>®</sup> (ciprofloxacin).

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

*ALLERX and RespiVent<sup>™</sup>, or RESPIVENT, Dose Pack Products* prescription products, including first generation antihistamine and antihistamine combination products, such as Capellon Pharmaceuticals, Ltd.'s Rescon-MX<sup>®</sup> (chlorpheniramine, methscopolamine and phenylephrine), Poly Pharmaceuticals, Inc.'s Poly Hist Forte<sup>®</sup> (chlorpheniramine, phenylephrine and pyrillamine) and Laser Pharmaceuticals, LLC's Dallerge<sup>®</sup> (phenylephrine, chlorpheniramine and methscopolamine); and over-the-counter products, such as McNeil PPC, Inc.'s Zyrtec<sup>®</sup> (cetirizine), Schering-Plough Corporation's Claritin<sup>®</sup> (loratadine) and Chlor-Trimeton<sup>®</sup> (chlorpheniramine) and McNeil PPC, Inc.'s Benadryl<sup>®</sup> (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<sup>™</sup>, or HYOMAX, Products* belladonna and derivative antispasmodics, such as the generic formulations of Alaven Pharmaceutical LLC's Levsin<sup>®</sup> (hyoscyamine sulfate) and Levbid<sup>®</sup> (hyoscyamine sulfate); synthetic gastrointestinal antispasmodics, such as the generic formulations of Axcan Pharma Inc.'s Bentyl<sup>®</sup> (dicyclomine) and Kenwood Therapeutics' Pamin<sup>®</sup> (methscopolamine bromide).

*Methscopolamine and Antihistamine Combination Product Candidate* second generation antihistamines, such as Sanofi-Aventis U.S. LLC's Allegra<sup>®</sup> (fexofenadine); third generation antihistamines, such as UCB, Inc. and Sanofi-Aventis U.S. LLC's Xyzal<sup>®</sup> (levocetirizine) and Schering-Plough Corporation's Clarinex<sup>®</sup> (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<sup>®</sup> (hydrocodone) and King Pharmaceuticals' Tussigon<sup>®</sup> (hydrocodone and homatropine), Mallinckrodt Medical Inc.'s TussiCap<sup>®</sup> (hydrocodone polistirex and chlorpheniramine polistirex) and UCB Pharma's Tussionex<sup>®</sup> (hydrocodone polistirex and chlorpheniramine polistirex); over-the-counter cough suppressants, such as Reckitt Benckiser's Delsym<sup>®</sup> (chlorpheniramine polistirex), Wyeth's Robitussin-DM<sup>®</sup> (dextromethorphan and guaifenesin) and Procter & Gamble Company's Vicks Formula 44<sup>®</sup> Cough Relief (dextromethorphan, phenylephrine and chlorpheniramine); and prescription cough suppressants, such as Sciele Pharma, Inc.'s Rondo<sup>®</sup> DM Syrup (chlorpheniramine, phenylephrine and dextromethorphan) and Meda Pharmaceuticals Inc.'s Tussi-12<sup>®</sup> (carbetapentane, pyrillamine 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.

*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



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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.

***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

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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 its 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 27-month shelf life, if demand does not meet or exceed Cornerstone's forecast over the next 21 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 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.

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***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 propoxyphene 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 product 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 methscopolamine and antihistamine 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 fourth quarter of 2008 and its hydrocodone cough suppressant product candidates CBP 067 and CBP 069 in 2009. Cornerstone cannot predict whether it will encounter

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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

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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

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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 and cold 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

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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 July 31, 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.



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***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.

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***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;

finest;

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.

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***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 84 employees as of July 31, 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;

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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 "Legal Proceedings" beginning on page 229 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

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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 Alre<sup>®</sup> 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 Alre<sup>®</sup> 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

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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

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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

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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.





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***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:

finer;

injunctive;

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

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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

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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

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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;

obtaining and maintaining regulatory approval for these product candidates; and

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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;

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

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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 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

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

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***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.

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***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 July 31, 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 50% 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

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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 23 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.



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**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 \_\_\_\_\_, 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**



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**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, , 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 327 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.

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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 149. 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

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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.

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**THE MERGER**

*This section and the section entitled **The Merger Agreement** beginning on page 134 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 335 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.

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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

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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

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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

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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 models for each company and pro forma models on a combined basis.

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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.

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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 Critical Therapeutics and Cornerstone, in each case utilizing different assumptions regarding future business plans and financing needs;

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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.

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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.

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, and Alastair McEwan, Chairman of the board of directors of Cornerstone, requested a meeting with David Price, a managing director of Jefferies, to solicit Jefferies' assistance in connection with a possible transaction with Critical Therapeutics.

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.

On March 7, 2008, Mr. Collard, Dr. Dickson and Mr. McEwan 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 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

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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, Critical Therapeutics' outside legal counsel, 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.

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.

Also on March 25, 2008, Critical Therapeutics, Cornerstone and their respective financial advisors held a telephone conference to discuss financial models for each company and pro forma models on a combined basis.

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, 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, Cornerstone delivered a legal due diligence request list to Critical Therapeutics regarding legal, finance and other business matters relating to Critical Therapeutics.

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

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Therapeutics and Cornerstone. Following these presentations, Cornerstone's representatives departed the meeting.

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, 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. 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.

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. 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.

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.

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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.

	<b>Projected for Critical Therapeutics</b>	
	<b>2008</b>	<b>2009</b>
	<b>(Unaudited, amounts in thousands)</b>	
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.

	<b>Projected for Cornerstone</b>	
	<b>2008</b>	<b>2009</b>
	<b>(Unaudited, amounts in thousands)</b>	
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 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.

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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.**

## **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.



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***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;

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;

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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;

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;

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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;

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

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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;

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;

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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;

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;

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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 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 description of material terms of Lazard's opinion set forth in this proxy statement/prospectus is qualified in its entirety by reference to the full text of Lazard's opinion. 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**

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**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

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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.

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.



**Table of Contents*****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 from the last three quarters of calendar year 2008 through the full calendar year 2015 utilizing internal estimates of Cornerstone's management, as 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:

<b>Implied Per Share Equity Reference Range for Cornerstone</b>	<b>Implied Per Share Merger Consideration</b>
\$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:

Bentley Pharmaceuticals, Inc.

K-V Pharmaceutical Company

Par Pharmaceutical Companies, Inc.

Salix Pharmaceuticals, Ltd.

Sciele Pharma, Inc.

Valeant Pharmaceuticals International

Lazard reviewed, among other things, enterprise values of the selected companies (which enterprise values ranged from approximately \$244 million to \$1.6 billion), 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, 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**

\$3.10 - \$4.05

**Implied Per Share  
Merger Consideration**

\$1.86

**Table of Contents*****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**

\$1.20 - \$1.95

**Per Share Closing Price of  
Critical Therapeutics Common Stock**

\$0.62

***Selected Publicly Traded Companies Analysis***

Lazard reviewed publicly available financial information for the following 10 publicly traded emerging specialty pharmaceutical companies:

Barrier Therapeutics, Inc.

Eurand N.V.

Indevus Pharmaceuticals, Inc.

Inspire Pharmaceuticals, Inc.

ISTA Pharmaceuticals, Inc.

Jazz Pharmaceuticals, Inc.

Noven Pharmaceuticals, Inc.

POZEN Inc.

Santarus, Inc.

Sucampo Pharmaceuticals, Inc.

Lazard reviewed, among other things, enterprise values of the selected companies (which enterprise values ranged from approximately \$73 million to \$724 million) 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

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information. 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. 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: