

CRITICAL THERAPEUTICS INC  
Form S-4  
July 22, 2008

As filed with the Securities and Exchange Commission on July 22, 2008  
Registration No. 333-

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

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

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**Critical Therapeutics, Inc.**  
**60 Westview Street**  
**Lexington, MA 02421**  
**Telephone: (781) 402-5700**  
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**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   
 (Do not check if a smaller reporting company)      Smaller reporting company

**CALCULATION OF REGISTRATION FEE**

<b>Title of Each Class of Securities to be Registered(1)</b>	<b>Amount to be Registered(2)</b>	<b>Proposed Maximum Offering Price per Share</b>	<b>Proposed Maximum Aggregate Offering Price(3)</b>	<b>Amount of Registration Fee</b>
Common stock, \$0.001 par value per share	101,450,013	N/A	\$29,420,504	\$1,156

- (1) This registration statement relates to common stock, \$0.001 par value per share, of Critical Therapeutics, Inc., a Delaware corporation ( Critical Therapeutics ), issuable to holders of common stock, \$0.0001 par value per share, of Cornerstone BioPharma Holdings, Inc., a Delaware corporation ( Cornerstone ), in the proposed merger of Neptune Acquisition Corp., a wholly owned subsidiary of Critical Therapeutics, with and into Cornerstone.
- (2) The amount of Critical Therapeutics common stock to be registered has been determined based on the estimated maximum number of shares to be issued in the merger, calculated by multiplying 2.3333 by 43,479,198 (the number of issued and outstanding shares of Critical Therapeutics common stock as of April 30, 2008). All of Critical Therapeutics common stock, including the securities covered by this registration statement, will be reclassified and combined by a reverse stock split into a lesser amount of Critical Therapeutics common stock, and the amount of undistributed common stock deemed to be covered by this registration statement shall be proportionately reduced.
- (3) Estimated solely for purposes of calculation of the registration fee in accordance with Rule 457(f) of the Securities Act of 1933, as amended, based upon the aggregate book value of Cornerstone securities that may be cancelled in the merger computed as of March 31, 2008, the latest practicable date prior to the date of filing of this registration statement.

**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 JULY 22, 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, 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 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**

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**to the merger agreement, FOR the amendment to Critical Therapeutics certificate of 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 17.**

**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- ) 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 297.

### 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™ and HyoMax™ 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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## TABLE OF CONTENTS

QUESTIONS AND ANSWERS ABOUT THE SPECIAL MEETING AND THE MERGER	v
SUMMARY	1
The Companies	1
Summary of the Merger	1
Reasons for the Merger	2
Opinion of Critical Therapeutics' Financial Advisor	2
Overview of the Merger Agreement	2
Stockholder Agreements and Noteholder Agreement	3
Management Following the Merger	4
The Board of Directors Following the Merger	4
Interests of Critical Therapeutics' Directors and Executive Officers	5
Interests of Cornerstone's Directors and Executive Officers	5
Stock Options and Warrants	5
Material U.S. Federal Income Tax Consequences of the Merger	5
Risk Factors	5
Regulatory Approvals	6
Anticipated Accounting Treatment	6
Appraisal Rights	6
Comparison of Stockholder Rights	6
SELECTED HISTORICAL AND PRO FORMA COMBINED FINANCIAL DATA	7
Selected Historical Consolidated Financial Data of Critical Therapeutics	8
Selected Historical Consolidated Financial Data of Cornerstone	10
Selected Unaudited Pro Forma Condensed Combined Financial Data of Critical Therapeutics and Cornerstone	12
Comparative Historical and Unaudited Pro Forma Per Share Data	14
MARKET PRICE AND DIVIDEND INFORMATION	15
RISK FACTORS	17
Risks Related to the Merger	17
Risks Related to Critical Therapeutics	19
Risks Related to Cornerstone	49
Risks Related to the Combined Company	75
FORWARD-LOOKING STATEMENTS	79
THE SPECIAL MEETING OF CRITICAL THERAPEUTICS' STOCKHOLDERS	80
Date, Time and Place	80
Purposes of the Special Meeting	80
Recommendation of Critical Therapeutics' Board of Directors	80
Record Date and Voting Power	81
Voting and Revocation of Proxies	81
Quorum and Required Vote	82
Solicitation of Proxies	83
Other Matters	83
THE MERGER	84
Background of the Merger	84
Financial Projections	90

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Critical Therapeutics Reasons for the Merger	92
Opinion of Critical Therapeutics Financial Advisor	95
Interests of Critical Therapeutics Directors and Executive Officers in the Merger	100
Interests of Cornerstone s Directors and Executive Officers in the Merger	104
Cornerstone Stock Options and Warrants	106
Form of the Merger	107
Merger Consideration	107
Effective Time of the Merger	108
Regulatory Approvals	108
Material U.S. Federal Income Tax Consequences of the Merger	109
NASDAQ Listing	111
Anticipated Accounting Treatment	112
Appraisal Rights	112
THE MERGER AGREEMENT	115
General	115
Merger Consideration	115
Amendments to Critical Therapeutics Certificate of Incorporation	115
Conditions to the Completion of the Merger	116
No Solicitation	118
Change in Recommendation	119
Meeting of Critical Therapeutics Stockholders	119
Covenants; Conduct of Business Pending the Merger	120
Other Agreements	124
Termination	125
Termination Fee	126
Representations and Warranties	127
Amendment	128
Cornerstone Operating Company Guarantee	128
AGREEMENTS RELATED TO THE MERGER	129
Cornerstone Stockholder Agreements	129
Cornerstone Noteholder Agreement	129
Critical Therapeutics Stockholder Agreements	129
MATTERS BEING SUBMITTED TO A VOTE OF CRITICAL THERAPEUTICS STOCKHOLDERS	130
Proposal 1: Approval of the Issuance of Common Stock in the Merger	130
Proposal 2: Approval of the Reverse Stock Split	130
Proposal 3: Approval of Name Change	136
Proposal 4: Approval of Possible Adjournment of the Special Meeting	137
CRITICAL THERAPEUTICS BUSINESS	138
Overview	138
Proposed Merger with Cornerstone	139
Critical Therapeutics Product Pipeline	139
Zileuton	139
Critical Care: The Inflammatory Response	145
Collaborations	147

Development	150
Sales and Marketing	150
Manufacturing and Supply	151
Distribution Network	154
License and Royalty Agreements	154
Proprietary Rights	158
Regulatory Matters	160
Competition	163
Properties	165
Employees	165
Access to SEC Filings	165
<b>CORNERSTONE S BUSINESS</b>	166
Overview	166
Strategy	166
Marketed Products	168
Other Products	172
Product Development Pipeline	175
Sales and Marketing; Co-promotion Agreements	179
Trade, Distribution and Reimbursement	181
Manufacturing	181
Intellectual Property	182
License and Collaboration Agreements	183
Competition	189
Regulatory Matters	190
Pharmaceutical Pricing and Reimbursement	198
Fraud and Abuse Regulation	199
Corporate Organization	200
Employees	200
Properties	200
Legal Proceedings	200
<b>CRITICAL THERAPEUTICS MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</b>	203
Overview	203
Financial Operations Overview	204
Critical Accounting Policies	208
Results of Operations	212
Liquidity and Capital Resources	224
Effects of Inflation	228
Recent Accounting Pronouncements	228
<b>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT CRITICAL THERAPEUTICS MARKET RISK</b>	230
<b>CORNERSTONE S MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</b>	231
Overview	231
Financial Operations Overview	234
Critical Accounting Estimates	238



Results of Operations	241
Liquidity and Capital Resources	248
Off-Balance Sheet Arrangements	252
Effects of Inflation	252
Recent Accounting Pronouncements	253
QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT CORNERSTONE S MARKET RISK MANAGEMENT FOLLOWING THE MERGER	255
Executive Officers and Directors	256
The Board of Directors	258
Certain Relationships and Related Transactions, and Director Independence	260
Executive Compensation and Other Information	261
Compensation Committee Interlocks and Insider Participation	273
UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION	274
DESCRIPTION OF CRITICAL THERAPEUTICS CAPITAL STOCK	282
Authorized Capital Stock	282
Common Stock	282
Preferred Stock	283
Delaware Law and Certificate of Incorporation and Bylaw Provisions	283
COMPARISON OF RIGHTS OF HOLDERS OF CRITICAL THERAPEUTICS STOCK AND CORNERSTONE S COMMON STOCK	285
PRINCIPAL STOCKHOLDERS OF CRITICAL THERAPEUTICS	290
PRINCIPAL STOCKHOLDERS OF CORNERSTONE	293
PRINCIPAL STOCKHOLDERS OF COMBINED COMPANY	295
LEGAL MATTERS	297
EXPERTS	297
WHERE YOU CAN FIND MORE INFORMATION	297
INDEX TO CRITICAL THERAPEUTICS CONSOLIDATED FINANCIAL STATEMENTS	F-1
INDEX TO CORNERSTONE S CONSOLIDATED FINANCIAL STATEMENTS	F-51

#### ANNEXES

AGREEMENT AND PLAN OF MERGER	A-1
CERTIFICATE OF AMENDMENT TO CRITICAL THERAPEUTICS CERTIFICATE OF INCORPORATION (REVERSE STOCK SPLIT)	B-1
CERTIFICATE OF AMENDMENT TO CRITICAL THERAPEUTICS CERTIFICATE OF INCORPORATION (NAME CHANGE)	C-1
OPINION OF LAZARD FRÈRES & CO. LLC	D-1
SECTION 262 OF THE DELAWARE GENERAL CORPORATION LAW	E-1
FORM OF CRITICAL THERAPEUTICS PROXY CARD	F-1

## 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. 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, 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. For a more complete description of the merger, please see the section entitled "The Merger Agreement" beginning on page 115 of this proxy statement/prospectus.

### **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.

### **Q: Why is Critical Therapeutics proposing to merge with Cornerstone?**

A: Critical Therapeutics' board of directors considered a number of factors that supported its decision to approve the merger agreement. 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.



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For a more complete discussion of Critical Therapeutics' reasons for the merger, please see the section entitled "The Merger - Critical Therapeutics' Reasons for the Merger" beginning on page 92 of this proxy statement/prospectus.

**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: What is required to consummate the merger?**

A: To consummate the merger, Critical Therapeutics' stockholders must approve (1) 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, (2) the amendment to Critical Therapeutics' certificate of incorporation to effect a reverse stock split of Critical Therapeutics' common stock, as described below, 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 (3) 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. Upon the effectiveness of the amendment to Critical Therapeutics' certificate of incorporation effecting the reverse stock split, the outstanding shares of Critical Therapeutics' common stock will be reclassified and combined into a lesser number of shares such that one share of Critical Therapeutics' common stock will be issued for a specified number of shares, which shall be greater than one and equal to or less than 50, of outstanding Critical Therapeutics' common stock, with the exact number within the range to be determined by Critical Therapeutics' board of directors prior to the effective time of such amendment and publicly announced by Critical Therapeutics. 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 in order to consummate the merger.

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. In addition to obtaining stockholder approval, each of the other closing conditions set forth in the merger agreement must be satisfied or waived. Among the closing conditions is approval by The NASDAQ Stock Market LLC, or 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 as set forth in the merger agreement. For a more complete description of the closing conditions under the merger agreement, please see the section entitled "The Merger Agreement - Conditions to the Completion of the Merger" beginning on page 116 of this proxy statement/prospectus.

**Q: Are there any federal or state regulatory requirements that must be complied with or federal or state regulatory approvals or clearances that must be obtained in connection with the merger?**

A: Neither Critical Therapeutics nor Cornerstone is required to make any filings or to obtain any 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. Prior to consummation of the merger, Critical Therapeutics intends to file an initial listing application with The NASDAQ Capital Market pursuant to NASDAQ's reverse merger rules 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.

**Q: What will Cornerstone's stockholders receive in the merger?**

A: The shares of Critical Therapeutics' common stock issued or issuable to Cornerstone's stockholders in connection with the merger are expected to represent approximately 70%, and shares of Critical Therapeutics' common stock held by Critical Therapeutics' current stockholders are expected to represent approximately 30%, of Critical Therapeutics' common stock, 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. 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 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. For a more complete discussion of the exchange ratio at the effective time of the merger, please see the section entitled "The Merger Agreement - Merger Consideration" beginning on page 115 of this proxy statement/prospectus.

**Q: Who will be the directors of Critical Therapeutics following the merger?**

A: 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.

**Q: Who will be the executive officers of Critical Therapeutics following the merger?**

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

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

**Q: What are the material federal income tax consequences of the merger to me?**

A: 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.

For a more complete description of the tax consequences of the merger, please see the section entitled "The Merger - Material U.S. Federal Income Tax Consequences of the Merger" beginning on page 109 of this proxy statement/prospectus.

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

A: After careful consideration, Critical Therapeutics' board of directors unanimously recommends that Critical Therapeutics' stockholders vote:

FOR Proposal 1 to approve the issuance of Critical Therapeutics' common stock pursuant to the merger agreement;

FOR Proposal 2 to approve an amendment to Critical Therapeutics' certificate of incorporation to effect the reverse stock split;

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 approve 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.

**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.

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.

viii

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**Q: What risks should Critical Therapeutics stockholders consider in deciding whether to vote in favor of the share issuance, reverse stock split and name change?**

A: Critical Therapeutics stockholders should carefully read the section of this proxy statement/prospectus entitled "Risk Factors" beginning on page 17, which sets forth certain risks and uncertainties related to the merger, risks and uncertainties to which the combined company's business will be subject and risks and uncertainties to which each of Critical Therapeutics and Cornerstone, as an independent company, is subject.

**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. For a more complete description of the closing conditions under the merger agreement, please see the section entitled "The Merger Agreement - Conditions to the Completion of the Merger" beginning on page 116 of this proxy statement/prospectus.

**Q: How will the merger affect stock options and warrants to acquire Cornerstone common stock?**

A: Upon the effectiveness of the merger, each outstanding option to purchase Cornerstone's common stock, whether vested or unvested, and all warrants to purchase Cornerstone's common stock will be assumed by Critical Therapeutics and become options and warrants to purchase Critical Therapeutics' common stock.

**Q: How will the reverse stock split and the merger affect stock options and warrants to acquire Critical Therapeutics common stock and Critical Therapeutics stock option plans?**

A: 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. 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. 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.

**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.

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: Am I entitled to appraisal rights?**

A: 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. For a more complete description of appraisal rights, please see the section entitled "The Merger - Appraisal Rights" beginning on page 112 of this proxy statement/prospectus.

**Q: Have Cornerstone's stockholders agreed to adopt the merger agreement?**

A: Yes. On May 2, 2008, by a majority of the votes represented by the outstanding shares of Cornerstone's common stock, Cornerstone's stockholders adopted the merger agreement by written consents in lieu of a meeting.

In addition, in connection with the execution of the merger agreement, holders of a majority of the shares of Cornerstone's outstanding common stock have entered into agreements with Critical Therapeutics that provide, among other things, that the stockholders vote in favor of the adoption of the merger agreement and grant to Critical Therapeutics an irrevocable proxy to vote all of such stockholders' shares of Cornerstone's common stock in favor of adoption of the merger agreement and against any proposal made in opposition to, or in any competition with, the merger. Furthermore, Carolina Pharmaceuticals Ltd., or Carolina Pharmaceuticals, which is a holder of that certain Promissory Note, dated April 19, 2004, as amended, or the Carolina Note, issued by a wholly owned subsidiary of Cornerstone, 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 shares of Cornerstone's common stock prior to the effective time of the merger and for the same voting provisions provided pursuant to the agreements entered into by Cornerstone's other stockholders.

**Q: Have any of Critical Therapeutics' stockholders agreed to vote in favor of the issuance of the shares in the merger?**

A: Yes. In connection with the execution of the merger agreement, funds managed by Healthcare Ventures and Advanced Technology Ventures, which own 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 all of such stockholders' shares of Critical Therapeutics' common stock in favor of the approval of the issuance of the shares 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.

**Q: Has Critical Therapeutics entered into any agreements with Cornerstone's stockholders and noteholders restricting the transfer of shares of Critical Therapeutics' common stock they receive in the merger?**

A: Yes. Pursuant to the agreements that Critical Therapeutics entered into with Cornerstone's stockholders described above, such stockholders have agreed not to transfer or otherwise dispose of any shares of Critical Therapeutics' common stock they receive in the merger for 180 days after the effective time of the merger. Carolina Pharmaceuticals also agreed to these lock-up provisions with respect to shares of Critical Therapeutics' common stock it receives in the merger following conversion or exchange of the outstanding principal amount of the Carolina Note.

**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:

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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).

## 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 297 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 drugs approved by the U.S. Food and Drug Administration, or FDA: ZYFLO CR<sup>®</sup> (zileuton) extended-release tablets, or ZYFLO CR, and ZYFLO<sup>®</sup> (zileuton tablets), or ZYFLO. Critical Therapeutics is developing products for acute asthma attacks that lead patients to the emergency room and other urgent care settings. Critical Therapeutics also is developing therapies directed toward the body's inflammatory response.

#### **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 51 person specialty sales force. Cornerstone's commercial strategy is to acquire non-promoted or underperforming branded pharmaceutical products and then maximize their potential value by promoting the products using its sales and marketing capabilities and applying various product life cycle management techniques. Cornerstone's product development pipeline consists of three line extensions of one of its currently marketed products and three other product candidates for the respiratory market. Cornerstone also generates revenue from the sale of six marketed product lines that include products that it does not promote.

### **Summary of the Merger (see page 84)**

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.

The shares of Critical Therapeutics' common stock issued or issuable to Cornerstone's stockholders in connection with the merger are expected to represent approximately 70%, and shares of Critical Therapeutics' common stock held by Critical Therapeutics' current stockholders are expected to represent approximately 30%, of Critical Therapeutics' common stock, 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. 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 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. For a more complete discussion of the exchange ratio at the effective time of the merger, please see the section entitled "The Merger Agreement - Merger Consideration" beginning on page 115 of this proxy statement/prospectus.

### **Reasons for the Merger (see page 92)**

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

### **Opinion of Critical Therapeutics' Financial Advisor (see page 95)**

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 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 115)***

Pursuant to the merger, Critical Therapeutics will issue to Cornerstone's stockholders, and will assume Cornerstone's 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, 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.

#### ***Conditions to Completion of the Merger (see page 116)***

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

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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 receipt of all authorizations, consents, orders or approvals of any governmental entity in connection with the consummation of the merger;



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 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 the Carolina Note 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.

***No Solicitation (see page 118)***

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

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

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

***Termination of the Merger Agreement (see page 125)***

Either Critical Therapeutics or Cornerstone can terminate the merger agreement under specified circumstances, which would prevent the merger from being consummated.

***Termination Fees and Expenses (see page 126)***

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 129)**

In connection with the execution of the merger agreement, holders of a majority 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, 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 shares of Cornerstone's common stock 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.

#### **Management Following the Merger (see page 256)**

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
George Esgro	Vice President, Sales and Marketing	Cornerstone's Vice President, Sales and Marketing
Brian Dickson, M.D.	Chief Medical Officer	Cornerstone's Chief Medical Officer
Steven M. Lutz	Executive Vice President, Manufacturing and Trade	Cornerstone's Executive Vice President, Commercial Operations
Chenyqua Baldwin	Vice President, Finance, Chief Accounting Officer and Controller	Cornerstone's Vice President, Finance

#### **The Board of Directors Following the Merger (see page 258)**

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

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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 100)**

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.

As of June 30, 2008, all directors and executive officers of Critical Therapeutics, together with their affiliates, beneficially owned approximately 23.0% 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 104)**

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.

**Stock Options and Warrants (see page 106)**

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, shares of Critical Therapeutics common stock.

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, shares of Critical Therapeutics common stock.

**Material U.S. Federal Income Tax Consequences of the Merger (see page 109)**

The merger has been structured to qualify as a reorganization within the meaning of Section 368(a) of 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 17)**

The merger, including the possibility that the merger may not be consummated, poses a number of risks to Critical Therapeutics and its stockholders. In addition, 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.

**Regulatory Approvals (see page 108)**

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. Prior to consummation of the merger, Critical Therapeutics intends to file an initial listing application with The NASDAQ Capital Market pursuant to NASDAQ's reverse merger rules and to effect the listing of Critical Therapeutics common stock issuable in connection with the merger or upon exercise of Cornerstone's outstanding stock options or warrants.

**Anticipated Accounting Treatment (see page 112)**

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 112)**

Under Delaware law, some of Cornerstone's stockholders are entitled to appraisal rights in connection with the merger. Critical Therapeutics' stockholders are not entitled to appraisal rights in connection with the merger.

**Comparison of Stockholder Rights (see page 285)**

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.

**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.



### 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 three months ended March 31, 2008 and 2007 and the balance sheet data as of March 31, 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.

	Three Months Ended		Year Ended December 31,				
	March 31, 2008	March 31, 2007	2007	2006	2005	2004	2003
(In thousands, except share and per share data)							
<b>Statements of Operations Data:</b>							
Net product sales	\$ 3,333	\$ 2,894	\$ 11,008	\$ 6,647	\$ 387	\$	\$
Revenue under licensing and co-development agreements		601	1,861	6,431	5,837	4,436	1,020
Total revenues	3,333	3,495	12,869	13,078	6,224	4,436	1,020
Cost of products sold	1,825	741	4,233	2,222	514		
Research and development	5,365	2,919	21,655	26,912	29,959	25,578	17,450
Selling and marketing	3,878	1,982	12,193	18,284	13,671	1,199	
General and administrative	3,215	3,056	13,572	13,456	11,406	9,679	3,770
Restructuring charges				3,498			
	14,281	8,696	51,653	64,372	55,550	36,456	21,220

total costs and expenses								
Operating loss	(10,948)	(5,201)	(38,784)	(51,294)	(49,326)	(32,020)	(20,200)	(20,200)
Interest income	218	590	2,020	2,726	2,427	1,098	19	19
Interest expense	(49)	(39)	(209)	(214)	(191)	(172)	(9)	(9)
Net loss	(10,779)	(4,650)	(36,973)	(48,782)	(47,090)	(31,094)	(20,110)	(20,110)
Retirement of dividends								
and offering costs on preferred stock						(2,209)	(2,260)	(2,260)
Net loss available to common stockholders	\$ (10,779)	\$ (4,650)	\$ (36,973)	\$ (48,782)	\$ (47,090)	\$ (33,303)	\$ (22,370)	\$ (22,370)
Net loss per common share:								
Basic and diluted	\$ (0.25)	\$ (0.11)	\$ (0.87)	\$ (1.37)	\$ (1.61)	\$ (2.28)	\$ (33.9)	\$ (33.9)
Weighted-average basic and diluted shares outstanding	42,805,348	42,456,700	42,580,884	35,529,048	29,276,243	14,631,371	658,200	658,200

	<b>March 31,</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	\$ 20,239	\$ 45,330	\$ 33,828	\$ 48,388	\$ 57,257	\$ 11,980	\$ 40,078
Short-term investments		650		650	25,554	66,849	
Working capital	17,098	44,306	26,380	47,738	70,005	64,357	25,218
Total assets	34,180	54,819	44,924	58,182	91,819	83,114	45,054
Long-term debt, net of current portion		229		421	1,489	1,367	720
Redeemable convertible preferred stock							51,395
Accumulated deficit	(202,151)	(159,049)	(191,372)	(154,399)	(105,617)	(58,527)	(27,433)
Total stockholders equity (deficit)	7,126	46,482	17,091	49,906	72,247	65,408	(24,851)

### 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 three months ended March 31, 2008 and 2007 and the balance sheet data as of March 31, 2008 and 2007 are derived from Cornerstone's unaudited consolidated financial statements, which are included in this proxy statement/prospectus beginning on page F-85. 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>Three Months Ended</b>		<b>Year Ended December 31,</b>			<b>March 30, 2004 (Inception) through December 31, 2004</b>
	<b>March 31, 2008</b>	<b>March 31, 2007</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	
	<b>(In thousands, except share and per share data)</b>					
<b>Statements of Operations Data:</b>						
Net revenues	\$ 9,445	\$ 8,688	\$ 28,071	\$ 22,117	\$ 17,470	\$ 5,740
Costs and expenses:						
Cost of product sales	565	668	3,300	2,151	3,437	2,076
Sales and marketing	3,908	2,053	10,391	7,120	13,889	2,867
Royalties	1,245	1,180	3,409	1,663	1,933	689
General and administrative	1,504	982	4,106	3,679	4,881	1,020
Research and development	98	5	948	249	266	
Amortization and depreciation	758	842	3,231	2,704	1,939	8
Other charges		109	245	3,581	1,000	
Total costs and expenses	8,078	5,839	25,630	21,147	27,345	6,660
Operating income (loss)	1,367	2,849	2,441	970	(9,875)	(920)
Other expenses:						

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Interest expense, net	(379)	(340)	(1,410)	(1,240)	(1,557)	(782)
Loss on marketable security			(324)			
Other expenses			(7)	(35)	(6)	
Income (loss) before income taxes	988	2,509	700	(305)	(11,438)	(1,702)
Provision for income taxes	(319)	(632)	(130)			
Net income (loss)	\$ 669	\$ 1,877	\$ 570	\$ (305)	\$ (11,438)	\$ (1,702)

	<b>March 31,</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	\$ 416	\$ 558	\$ 241	\$ 116	\$ 959	\$ 4,008
Working capital	(4,634)	(6,537)	(5,131)	(9,230)	(11,740)	652
Total assets	16,746	14,289	15,909	10,582	16,147	21,019
Long-term debt, net of current portion	12,371	10,382	12,371	10,382	13,031	13,074
Accumulated deficit	(12,429)	(11,791)	(13,098)	(13,668)	(13,140)	(1,702)
Total stockholders deficit	(11,542)	(11,918)	(12,295)	(13,844)	(12,903)	(1,654)

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

(In thousands)

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 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 three months ended March 31, 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 March 31, 2008, giving effect to the combination as if it occurred on March 31, 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 297 of this proxy statement/prospectus for more information.

<b>For the Three Months Ended March 31, 2008</b>	<b>For The Year Ended December 31, 2007</b>
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**Unaudited Pro Forma Condensed Combined**

**Statement of Operations Data:**

Revenues	\$	12,195	\$	40,308
Operating expenses:				
Cost of product sold		3,635		10,942
Research and development		5,462		22,603
Selling, general and administrative		15,116		45,150
Total costs and expenses		24,213		78,695
Other income (expense)		(209)		70
Income (loss) before income taxes		(12,227)		(38,317)
Provision for income taxes		(319)		(130)
Net income (loss)	\$	(12,546)	\$	(38,447)



**As of  
March 31,  
2008**

**Unaudited Pro Forma Condensed Combined Balance Sheet Data:**

Cash and cash equivalents	\$ 18,929
Working capital	12,843
Total assets	58,288
Total liabilities	34,472
Total stockholders' equity	23,816

### 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 Critical Therapeutics Proposal No. 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 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 three months ended March 31, 2008 and for the year ended December 31, 2007 are derived from the unaudited pro forma condensed combined financial information beginning on page 275 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 274 of this proxy statement/prospectus.

#### CRITICAL THERAPEUTICS

	<b>Year Ended December 31, 2007</b>	<b>Three Months Ended March 31, 2008</b>
<b>Historical Per Common Share Data:</b>		
Net loss per common share - basic and diluted	\$ (0.87)	\$ (0.25)
Book value per share	\$ 0.40	\$ 0.17

#### CORNERSTONE

	<b>Year Ended December 31, 2007</b>	<b>Three Months Ended March 31, 2008</b>
<b>Historical Per Common Share Data:</b>		
Net income per common share - basic and diluted	\$ 0.02	\$ 0.02
Book value per share	\$ (0.49)	\$ (0.29)

**CORNERSTONE AND CRITICAL THERAPEUTICS**

		<b>Year Ended December 31, 2007</b>	<b>Three Months Ended March 31, 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)	\$ (0.08)
Book value per combined common share		\$ 0.21	\$ 0.17
<b>Equivalent Pro Forma Per Common Share Data:</b>			
Net loss per combined common share from continuing operations	basic and diluted	\$ (0.96)	\$ (0.19)
Book value per combined common share		\$ 0.60	\$ 0.41

**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	0.69	0.26
Third Quarter (through July 15, 2008)	0.42	0.33

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 \$62,930,000, 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



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.

## 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

***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 initial 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 a number of material risks, and its business and stock price could be adversely affected, as follows:

Critical Therapeutics has incurred and expects to continue to incur significant expenses related to the proposed merger with Cornerstone even if the merger is not consummated.

The merger agreement contains covenants relating to Critical Therapeutics' solicitation of competing acquisition proposals and the conduct of Critical Therapeutics' business between the date of signing the merger agreement and the closing of the merger. As a result, significant business decisions and transactions before the closing of the merger require the consent of Cornerstone. Accordingly, Critical Therapeutics may be unable to pursue business opportunities that would otherwise be in its best interest as a standalone company. If the merger agreement is terminated after Critical Therapeutics has invested significant time and resources in the transaction process, 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' 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.

Some of Critical Therapeutics' suppliers, distributors and other business partners may seek to change or terminate their relationships with Critical Therapeutics 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 Critical Therapeutics' ability to retain its key employees, who may seek other employment opportunities.

Critical Therapeutics' management team may be distracted from day to day operations as a result of the proposed merger.

The market price of Critical Therapeutics common stock may decline 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.



***Some of Critical Therapeutics and Cornerstone's officers and directors have conflicts of interest that may 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. 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 100 and 104, 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.

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 the combined company's common stock may decline as a result of the merger.***

The market price of the combined company's common stock may decline as a result of the merger 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.***

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.

***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. As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors. In addition, 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.

***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 49 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 49 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 August 2008 to help manage the potential impact to patients of supply chain issues for ZYFLO CR. 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 their patients' 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 February 2008, prescription data for ZYFLO indicates that approximately 5,757 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 \$711,000 for the three months ended March 31, 2008. Critical Therapeutics recorded revenue from the sale of ZYFLO CR of \$2.3 million for the year ended December 31, 2007 and \$2.6 million for the three months ended March 31, 2008. Critical Therapeutics experienced difficulty expanding the prescriber and patient base 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 pill 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 pills 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.

Market perceptions about the safety of ZYFLO 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.

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 many instances, ZYFLO CR has been positioned on a third-tier status, which typically requires the highest co-pay for patients. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for ZYFLO CR.

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

***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™ (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 three months ended March 31, 2008, Critical Therapeutics did not receive any co-promotion fees from DEY in connection with the PERFOROMIST co-promotion agreement because the level of quarterly retail sales for PERFOROMIST did not exceed a specified level. On July 2, 2008, Critical Therapeutics provided notice to DEY that Critical Therapeutics had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

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

Critical Therapeutics is subject to minimum purchase obligations under its supply agreements with its third-party manufacturers, which require Critical Therapeutics to buy inventory of the zileuton active pharmaceutical ingredient, or API, and tablet cores for ZYFLO CR. 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 March 31, 2008, Critical Therapeutics had \$9.7 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 quarters ended December 31, 2007 and March 31, 2008, Critical Therapeutics recorded an inventory reserve for an aggregate of eight batches of ZYFLO CR that cannot be released into Critical Therapeutics' commercial supply chain because the batches did not meet Critical Therapeutics' product release specifications. 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.

***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.

***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, 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.

***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 or research institutions.

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

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

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

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

If Critical Therapeutics' therapeutic programs directed toward the body's inflammatory response result in commercial products, such products will compete predominantly with therapies that have been approved for diseases such as rheumatoid arthritis, like Amgen, Inc.'s Enbrel®, Johnson & Johnson's Remicade®, Bristol-Myers Squibb Company's Orencia®, Abbott Laboratories' Humira® and Rituxan® marketed by Biogen Idec Inc. and Genentech, Inc., and

diseases such as sepsis, like Eli Lilly and Company's Xigris®. Other companies are developing therapies directed towards cytokines. Critical Therapeutics does not know whether any or all of these products under development will ever reach the market and if they do, whether they will do so before or after Critical Therapeutics' products are approved.

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

significantly greater financial, technical and human resources than Critical Therapeutics has and may be better equipped to discover, develop, manufacture and commercialize products;

more extensive experience than Critical Therapeutics has in conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;

competing products that have already received regulatory approval or are in late-stage development; and

collaborative arrangements in Critical Therapeutics' target markets with leading companies and research institutions.

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

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

Critical Therapeutics' success depends in large part on its ability to attract, retain and motivate qualified management and commercial personnel. Critical Therapeutics is highly dependent on the principal members of its executive management team. The loss of the services of any one or more of the members of Critical Therapeutics' executive management team would diminish the knowledge and experience that Critical Therapeutics, as an organization, possesses and might significantly delay or prevent the achievement of Critical Therapeutics' research, development or commercialization objectives and could cause Critical Therapeutics to incur additional costs to recruit replacement executive personnel. Critical Therapeutics does not maintain key person life insurance on any of the members of Critical Therapeutics' 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 Critical Therapeutics publicly announced in November 2007 that Critical Therapeutics was in the process of reviewing a range of strategic alternatives that could result in potential changes to its current business strategy and future operations. The pendency of Critical Therapeutics' proposed merger with Cornerstone could have a similar effect. In June 2008, Critical Therapeutics reduced the size of its sales force by eight sales representatives and three sales managers. If Critical Therapeutics is not successful in its efforts to retain its remaining qualified sales and marketing personnel, Critical Therapeutics' ability to market and sell ZYFLO CR and Critical Therapeutics' ability to deliver Critical Therapeutics' required level of promotional detailing under Critical Therapeutics' co-promotion agreements with DEY would be impaired.

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

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

In connection with the preparation of Critical Therapeutics' financial statements for the second quarter of 2007, Critical Therapeutics identified a material weakness in its internal control over financial reporting. 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 controls over financial reporting for the year ended December 31, 2007. There were no material changes in Critical Therapeutics' internal control over financial reporting for the quarter ended March 31, 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.

***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 healthcare benefit program, including private payors and, further, requires us 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 healthcare 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 practice of medicine by non-physicians and fee-splitting arrangements between physicians and non-physicians, as well as state law equivalents to the federal Medicare and Medicaid anti-kickback laws, which may not be limited to government reimbursed items or services.

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

investigation of Critical Therapeutics' rebate practices could be costly, could divert the attention of Critical Therapeutics' management and could damage Critical Therapeutics' reputation.

If Critical Therapeutics' past or present operations are found to be in violation of any of the laws described above or other laws or governmental regulations to which Critical Therapeutics or its customers are subject, Critical Therapeutics may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from Medicare and Medicaid programs and curtailment or restructuring of Critical Therapeutics' operations. Similarly, if Critical Therapeutics' customers are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on Critical Therapeutics. In addition, if Critical Therapeutics is required to obtain permits or licenses under these laws that Critical Therapeutics does not already possess, Critical Therapeutics may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of Critical Therapeutics' operations would adversely affect its ability to operate its business and its financial results. Healthcare 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 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 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



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 healthcare practitioners. Similar legislation is being considered in a number of other states. Many of these requirements are new and uncertain, and available guidance is limited. Critical Therapeutics is in the process of identifying the universe of state laws applicable to pharmaceutical companies and is taking steps to ensure that Critical Therapeutics comes into compliance with all such laws. Unless and until Critical Therapeutics is in full compliance with these laws, Critical Therapeutics could face enforcement action and fines and other penalties, and could receive adverse publicity, all of which could materially harm Critical Therapeutics' business.

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

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

***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 Critical Therapeutics' other 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 49 employees as of June 30, 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 us 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 Critical Therapeutics' internal control systems in order to allow Critical Therapeutics' management to report on, and

Critical Therapeutics registered public accounting firm to attest to, Critical Therapeutics internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. If the controls and procedures that Critical Therapeutics has implemented do not comply with all of the



relevant rules and regulations of the SEC and NASDAQ, Critical Therapeutics may be subject to sanctions or investigation by regulatory authorities, including the SEC or NASDAQ. This type of action could adversely affect Critical Therapeutics' financial results or investors' confidence in Critical Therapeutics and Critical Therapeutics' ability to access the capital markets and could result in the delisting of Critical Therapeutics' common stock from NASDAQ. If Critical Therapeutics fails to develop and maintain adequate controls and procedures, Critical Therapeutics may be unable to provide the required financial information in a timely and reliable manner, which could cause a decline in Critical Therapeutics' stock price.

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

Critical Therapeutics' sales of ZYFLO CR and ZYFLO are, and any future sales of Critical Therapeutics' product candidates will be, dependent, in part, on the availability of reimbursement from third-party payors such as state and federal governments, under programs such as Medicare and Medicaid, and private insurance plans. There have been, there are and Critical Therapeutics expects there will continue to be, state and federal legislative and administrative proposals that could limit the amount that state or federal governments will pay to reimburse the cost of pharmaceutical and biologic products. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, was signed into law in December 2003. Legislative or administrative acts that reduce reimbursement for Critical Therapeutics' products could adversely impact Critical Therapeutics' business. In addition, Critical Therapeutics believes that private insurers, such as MCOs, may adopt their own reimbursement reductions in response to legislation. Any reduction in reimbursement for Critical Therapeutics' products could materially harm Critical Therapeutics' results of operations. In addition, Critical Therapeutics believes that the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of Critical Therapeutics' products, which may adversely impact Critical Therapeutics' product sales. Furthermore, when a new drug product is approved, governmental and private reimbursement for that product, and the amount for which that product will be reimbursed, are uncertain. Critical Therapeutics cannot predict the availability or amount of 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, healthcare institutions and other government agencies continue to seek price discounts. Because MCOs, HMOs and 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 citizen and drug programs for people with low incomes, including price or patient reimbursement constraints, restrictions on access to certain products, and bulk purchasing of drugs.

If Critical Therapeutics succeeds in bringing products in addition to ZYFLO CR and ZYFLO to the market, these products may not be considered cost-effective, and reimbursement to the patient may not be available or sufficient to allow Critical Therapeutics to sell its product candidates on a competitive basis to a sufficient patient population. Because Critical Therapeutics' product candidates are in the development stage, Critical Therapeutics is unable at this time to determine the cost-effectiveness of these product candidates. Critical Therapeutics may need to conduct expensive pharmacoeconomic trials in order to demonstrate their cost-effectiveness. Sales of prescription drugs are

highly dependent on the availability and level of reimbursement to the consumer from third-party payors, such as government and private insurance plans. These third-party

payors frequently require that drug companies provide them with predetermined discounts or rebates from list prices, and third-party payors are increasingly challenging the prices charged for medical products. Because Critical Therapeutics' product candidates are in the development stage, Critical Therapeutics does not know the level of reimbursement, if any, it will receive for those product candidates if they are successfully developed. If the reimbursement Critical Therapeutics receives for any of its product candidates is inadequate in light of Critical Therapeutics' development and other costs, Critical Therapeutics' ability to realize profits from the affected product candidate would be limited. If reimbursement for Critical Therapeutics' marketed products changes adversely or if Critical Therapeutics fails to obtain adequate reimbursement for its other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of Critical Therapeutics' products or cause Critical Therapeutics to reduce the price of its products.

***Critical Therapeutics' business has a substantial risk of product liability claims. If Critical Therapeutics is unable to obtain appropriate levels of insurance, a product liability claim against Critical Therapeutics could interfere with the development and commercialization of Critical Therapeutics' product candidates or subject Critical Therapeutics to unanticipated damages or settlement amounts.***

Critical Therapeutics' business exposes it to significant potential product liability risks that are inherent in the development, manufacturing and marketing and sale of drugs. If the use of ZYFLO CR, ZYFLO or one or more of Critical Therapeutics' other product candidates harms people, Critical Therapeutics may be subject to costly and damaging product liability claims. Critical Therapeutics currently has a \$20.0 million annual aggregate limit for insurance covering both product liability claims for ZYFLO CR and ZYFLO and clinical trial liability claims for Critical Therapeutics' product candidates. Critical Therapeutics may seek additional product liability insurance prior to marketing any of its other product candidates still in development. However, Critical Therapeutics' insurance may not provide adequate coverage against potential liabilities. Furthermore, product liability and clinical trial insurance is becoming increasingly expensive. As a result, Critical Therapeutics may be unable to maintain current amounts of insurance coverage, obtain additional insurance or obtain sufficient insurance at a reasonable cost to protect against losses that Critical Therapeutics has not anticipated in its business plans. Any product liability claim against Critical Therapeutics, even if Critical Therapeutics successfully defends against it, could cause Critical Therapeutics to incur significant legal expenses, divert Critical Therapeutics' management's attention and harm Critical Therapeutics' reputation.

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

***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 market 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. Critical Therapeutics has had only limited experience in preparing applications and obtaining regulatory approvals and clearances. Adverse side effects of a product candidate in a clinical trial could result in the FDA or foreign regulatory authorities refusing to approve or clear a particular product candidate for any or all indications for use.

The FDA and foreign regulatory agencies have substantial discretion in the drug approval process and can deny, delay or limit approval of a product candidate for a variety of reasons. If Critical Therapeutics does not receive the required regulatory approval or clearance to market any of Critical Therapeutics 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.

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

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

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

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

Critical Therapeutics cannot predict whether it will encounter problems with any of its completed, ongoing or planned clinical trials that will cause regulatory authorities, institutional review boards 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 clinical research organizations to supervise or monitor some or all aspects of the clinical trials for the product candidates Critical Therapeutics advances into clinical testing. Accordingly, Critical Therapeutics has less control over the timing and other aspects of these clinical trials than if Critical Therapeutics conducted them entirely on its own.

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

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

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

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

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

product seizures;

voluntary or mandatory recalls;

suspension of review or refusal to approve pending applications;

voluntary or mandatory patient or physician notification;

withdrawal of product approvals;

restrictions on, or prohibitions against, marketing Critical Therapeutics product candidates;

restrictions on applying for or obtaining government bids;

fines;

restrictions on importation of Critical Therapeutics product candidates;

injunctions; and

civil and criminal penalties.

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

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

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

co-promotion arrangement, including as a result of the sale or potential sale of DEY by Mylan, would limit Critical Therapeutics' ability to generate significant revenues from product sales. Furthermore, if DEY does not have sufficient sales capabilities, as a result of difficulty retaining or hiring sales representatives following Mylan's announcement that it is pursuing strategic alternatives for DEY or otherwise, then DEY may not be able to meet its minimum detailing obligations under the co-promotion agreement.

*Critical Therapeutics depends on MedImmune and Beckman Coulter and expects to depend on additional collaborators in the future for a portion of Critical Therapeutics' revenues and to develop, conduct*

*clinical trials with, obtain regulatory approvals for, and manufacture, market and sell some of Critical Therapeutics product candidates. These collaborations may not be successful.*

Critical Therapeutics is relying on MedImmune, Inc., a wholly owned subsidiary of AstraZeneca PLC, or MedImmune, to fund the development of and to commercialize product candidates in Critical Therapeutics high mobility group box protein 1, or 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 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 Critical Therapeutics arrangement, and Critical Therapeutics was unable to enter into a similar collaboration agreement with another qualified third party in a timely manner or devote sufficient financial resources or capabilities to continue development and commercialization on its own, the development and commercialization of Critical Therapeutics HMGB1 program likely would be delayed, curtailed or terminated. The delay, curtailment or termination of Critical Therapeutics HMGB1 program could significantly harm Critical Therapeutics future prospects.

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

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

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

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

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

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

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

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

Critical Therapeutics intends 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.

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

Critical Therapeutics has licensed to Innovative Metabolics, Inc., or IMI, patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. IMI is an early-stage company. Critical Therapeutics is not involved in IMI's efforts to develop and commercialize a medical device based on the intellectual property that Critical Therapeutics licensed to IMI. Critical Therapeutics will receive additional payments under the IMI license only if IMI 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.

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

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

Critical Therapeutics has contracted with Shasun Pharma Solutions Ltd., or Shasun, for commercial production of the zileuton API, subject to specified limitations, through December 31, 2010. Zileuton API is used in Critical Therapeutics' FDA-approved oral zileuton products, ZYFLO CR and ZYFLO, as well as in Critical Therapeutics

zileuton injection product candidate. Critical Therapeutics' only source of supply for zileuton API is Shasun, which manufactures the zileuton API in the United Kingdom. The manufacturing process for the zileuton API involves an exothermic reaction that generates heat and, if not properly controlled by the safety and protection mechanisms in place at the manufacturing sites, could result in unintended combustion of the product. The manufacture of the zileuton API could be disrupted or delayed if a batch is discontinued or damaged, if the manufacturing sites are damaged, or if local health and safety regulations require a third-



party manufacturer to implement additional safety procedures or cease production. In addition, there is only one qualified supplier of a chemical known as 2-ABT, which is one of the starting materials for zileuton, and if that manufacturer stops manufacturing 2-ABT, is unable to manufacture 2-ABT or is unwilling to manufacture 2-ABT on commercially reasonable terms or at all, Shasun may be unable to manufacture API for Critical Therapeutics.

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

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

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

The zileuton API is manufactured in the United Kingdom by Shasun, and Critical Therapeutics either stores the zileuton API at a Shasun warehouse, or ships the zileuton API either directly to a contract manufacturer or to a third-party warehouse. For the manufacture of ZYFLO CR, Critical Therapeutics ships zileuton API to France for

manufacturing of core tablets by Jagotec and Critical Therapeutics ships core tablets from France to the United States to be coated, packaged and labeled at Patheon. For the manufacture of ZYFLO, Critical Therapeutics ships zileuton API to the United States to be manufactured, packaged and labeled at Patheon. While in transit, Critical Therapeutics zileuton API and ZYFLO CR core tablets, each shipment of which is of significant value, could be lost or damaged. Moreover, at any time after shipment from Shasun, Critical Therapeutics zileuton API, which is stored in France at Jagotec or in the United States at Patheon or at third-

party warehouse, or Critical Therapeutics ZYFLO CR core tablets, which are stored at Patheon prior to coating and packaging, and Critical Therapeutics finished ZYFLO CR and ZYFLO products, which are stored at Critical Therapeutics third-party logistics provider, Integrated Commercialization Solutions, Inc., or ICS, could be lost or suffer damage, which would render them unusable. Critical Therapeutics has attempted to take appropriate risk mitigation steps and to obtain transit insurance. However, depending on when in the process the zileuton API, ZYFLO CR core tablets or finished product is lost or damaged, Critical Therapeutics may have limited recourse for recovery against its manufacturers or insurers. As a result, Critical Therapeutics financial performance could be impacted by any such loss or damage to its zileuton API, ZYFLO CR core tablets or finished products.

Critical Therapeutics may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. If Critical Therapeutics were required to change manufacturers for the zileuton API, ZYFLO CR tablet cores, ZYFLO or ZYFLO CR or coating, Critical Therapeutics would be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and all applicable regulations and guidelines, including FDA requirements and approved NDA product specifications. In addition, Critical Therapeutics would be required to conduct additional clinical bioequivalence trials to demonstrate that the finished product manufactured by the new manufacturer is equivalent to the finished product manufactured by Critical Therapeutics current manufacturer. Any delays associated with the verification of a new 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. 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 quarters ended December 31, 2007 and March 31, 2008, Critical Therapeutics recorded an inventory reserve with respect to an aggregate of eight batches of ZYFLO CR that cannot be released into Critical Therapeutics commercial supply chain because they did not meet Critical Therapeutics product release specifications. In conjunction with Critical Therapeutics three third-party manufacturers for zileuton API, tablet cores and coating and release, Critical Therapeutics has initiated an investigation to determine the cause of this issue, but the investigation is ongoing and is not yet complete. Critical Therapeutics has incurred and expects to continue to incur significant costs in connection with its investigation. To date, the investigation has not identified a clear source of the issue. As of June 30, 2008, Critical Therapeutics recorded an inventory reserve with respect to seven additional batches of the tablet cores of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. 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. As of July 18, 2008, Critical Therapeutics does not have available any additional supplies of finished ZYFLO CR tablets to ship to its wholesale distributors though eight additional batches are currently in process and may be releasable once release specification testing is completed. 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, Critical Therapeutics estimates that wholesale distributors and retail pharmacies have a sufficient inventory of ZYFLO CR to continue to provide product to patients through the end of August 2008.

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 August 2008 to help manage the potential impact to patients of supply chain issues for ZYFLO CR. However, reintroducing ZYFLO to replace ZYFLO CR could be confusing for physicians and patients. As a result of potential physician and patient 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.

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 March 31, 2008, Critical Therapeutics has expensed \$1.2 million relating to the eight batches that failed to meet product release specifications and Critical Therapeutics expects to incur other significant costs in connection with its investigation, including with respect to the seven additional batches of the tablet cores of ZYFLO CR for which Critical Therapeutics recorded an inventory reserve as of June 30, 2008. Critical Therapeutics anticipates that, as a result of the timing of the investigation, it will need to expense additional inventory that is unlikely to be sold. 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.

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 harm Critical Therapeutics' business.***

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

Critical Therapeutics relies on Phoenix Marketing Group LLC, or Phoenix, to distribute product samples to Critical Therapeutics' sales representatives, who in turn distribute samples to physicians and other prescribers who are authorized under state law to receive and dispense samples. Critical Therapeutics relies on RxHope to distribute samples of ZYFLO CR 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, Phoenix and RxHope, 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, Phoenix or RxHope 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 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 could be severely compromised and Critical Therapeutics' business could be harmed.

***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 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 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 efforts to enter into a collaboration arrangement with respect to a product candidate, Critical Therapeutics may not have sufficient funds to develop any of its product candidates internally. If Critical Therapeutics does not have sufficient funds to develop its product candidates, Critical Therapeutics will not be able to bring these product candidates to market and generate revenue. In addition, Critical Therapeutics' inability to enter into collaboration agreements could delay or preclude the development, manufacture and/or commercialization of a product candidate and could have a material adverse effect on Critical Therapeutics' financial condition and results of operations because:

Critical Therapeutics may be required to expend its own funds to advance the product candidate to commercialization;

revenue from product sales could be delayed; or

Critical Therapeutics may elect not to develop or commercialize the product candidate.

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

For product candidates with large target physician markets, Critical Therapeutics plans to rely significantly on sales, marketing and distribution arrangements with third parties. For example, Critical Therapeutics 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 Intellectual Property and Licenses

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

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

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

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

Critical Therapeutics pending patent applications and those of its licensors may not result in issued patents. In addition, the patent positions of pharmaceutical or biotechnology companies, including Critical Therapeutics, are generally uncertain and involve complex legal and factual considerations. The standards that the U.S. Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, Critical Therapeutics does not know the degree of future protection for its proprietary rights or the breadth of claims that will be allowed in any patents issued to Critical Therapeutics or to others with respect to its products in the future.

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

Critical Therapeutics confidentiality agreements with its current and potential collaborators, employees, consultants, strategic partners, outside scientific collaborators and sponsored researchers and other advisors may not effectively prevent disclosure of Critical Therapeutics confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary

to enforce and determine the scope of Critical Therapeutics' proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect Critical Therapeutics' competitive business position.

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

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

the patentability of Critical Therapeutics' applications, including those relating to Critical Therapeutics products; or

the enforceability, validity or scope of protection offered by Critical Therapeutics' patents, including those relating to Critical Therapeutics' products.

These proceedings are costly and time consuming. Critical Therapeutics may not have sufficient resources to bring these actions or to bring such actions to a successful conclusion. Even if Critical Therapeutics is successful in these proceedings, Critical Therapeutics may incur substantial cost and divert 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 Critical Therapeutics' 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 Critical Therapeutics' operations. In addition, Critical Therapeutics' MedImmune collaboration 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 Critical Therapeutics' 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.

#### **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 \$10.8 million in the three months ended March 31, 2008 and \$4.7 million in the three months ended March 31, 2007. As of March 31, 2008, Critical Therapeutics had an accumulated deficit of approximately \$202 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 \$3.3 million for the three months ended March 31, 2008 and have not recorded revenue from any other product. Critical Therapeutics expects that it will continue to incur substantial losses for the foreseeable future as Critical Therapeutics spends significant amounts to fund its research, 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 marketing ZYFLO CR;

the scope, costs and results of Critical Therapeutics' clinical trials;

the amount and timing of sales and returns of ZYFLO CR and ZYFLO;

the costs of ongoing sales, marketing and manufacturing activities for ZYFLO CR and ZYFLO;

the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals for Critical Therapeutics' other product candidates;

the timing, receipt and amount of milestone and other payments, if any, from DEY, MedImmune, Beckman Coulter, IMI 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 DEY and MedImmune, 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 and anticipated payments received under collaboration agreements 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 \$13.9 million for the three months ended March 31, 2008, and Critical Therapeutics had minimal capital expenditures. If Critical Therapeutics' existing resources are insufficient to satisfy its liquidity requirements or if Critical Therapeutics acquires or licenses rights to additional 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. In addition, the terms of the financing may adversely affect the holdings or the rights of Critical Therapeutics stockholders. For example, if Critical Therapeutics raises additional funds by issuing equity securities, further dilution to Critical Therapeutics' then-existing stockholders will result. 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. Critical Therapeutics also could be required to seek funds through arrangements with collaborators or others that may require Critical Therapeutics to relinquish rights to some of its technologies, product candidates or products, which Critical Therapeutics would otherwise pursue on its own.

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 Critical Therapeutics' 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 Critical Therapeutics' Common Stock**

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

The market price of Critical Therapeutics' common stock may fluctuate significantly in response to factors that are beyond Critical Therapeutics' control. The stock market in general has recently experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of Critical Therapeutics' common stock, which could cause a decline in the value of Critical Therapeutics' common stock.

***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.

If Critical Therapeutics fails to continue to meet all applicable listing requirements of The NASDAQ Capital Market in the future 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 Therapeutic 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 IMI and, to the extent

applicable, other licensing and collaboration agreement;

the results of ongoing and planned clinical trials of Critical Therapeutics product candidates;

production problems occurring at Critical Therapeutics third-party manufacturers;

the results of regulatory reviews relating to the development or approval of Critical Therapeutics product candidates; and

general and industry-specific economic conditions that may affect Critical Therapeutics research and development expenditures.

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

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

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

developments with respect to Critical Therapeutics' proposed merger with Cornerstone;

Critical Therapeutics' operating results, including the amount and timing of sales of ZYFLO CR and ZYFLO;

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.

***Insiders have substantial control over Critical Therapeutics and could delay or prevent a change in corporate control, including a transaction in which Critical Therapeutics' stockholders could sell or exchange their shares for a premium.***

As of June 30, 2008, Critical Therapeutics' directors, executive officers and 10% or greater stockholders, together with their affiliates, to Critical Therapeutics' knowledge, beneficially owned, in the aggregate, approximately 23.1% of Critical Therapeutics' outstanding common stock. As a result, Critical Therapeutics' 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 Critical Therapeutics' stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of Critical Therapeutics' assets. In addition, these persons, acting together, may have the ability to control the management and affairs of Critical Therapeutics' company. Accordingly, this concentration of ownership may harm the market price of Critical Therapeutics' common

stock by:

delaying, deferring or preventing a change in control of Critical Therapeutics;

impeding a merger, consolidation, takeover or other business combination involving Critical Therapeutics; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of Critical Therapeutics.

***Anti-takeover provisions in Critical Therapeutics charter documents and under Delaware law could prevent or frustrate attempts by Critical Therapeutics stockholders to change Critical Therapeutics management or Critical Therapeutics board and hinder efforts by a third party to acquire a controlling interest in Critical Therapeutics.***

Critical Therapeutics is incorporated in Delaware. Anti-takeover provisions of Delaware law and Critical Therapeutics 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 Critical Therapeutics is subject include provisions in Critical Therapeutics bylaws and certificate of incorporation providing that, except as otherwise required by law, special meetings of the stockholders may be called only by Critical Therapeutics 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 Critical Therapeutics bylaws providing for the classification of Critical Therapeutics board of directors.

Additionally, Critical Therapeutics board of directors has 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 Critical Therapeutics stockholders. The rights of holders of Critical Therapeutics common stock are subject to the rights of the holders of any preferred stock that Critical Therapeutics issues. As a result, Critical Therapeutics issuance of preferred stock could cause the market value of Critical Therapeutics common stock to decline and could make it more difficult for a third party to acquire a majority of Critical Therapeutics 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. Critical Therapeutics board of directors may use this provision to prevent changes in Critical Therapeutics management. Also, under applicable Delaware law, Critical Therapeutics board of directors may adopt additional anti-takeover measures in the future.

## **Risks Related to Cornerstone**

### **Risks Relating to Commercialization and Acquisitions**

***Cornerstone has derived substantially all of its revenue from sales of ALLERX, SPECTRACEF and BALACET 325.***

Cornerstone has derived and expects for the foreseeable future to continue to derive substantially all of its revenue from sales of AlleRx<sup>®</sup>, or ALLERX, Dose Pack products, Spectracef<sup>®</sup> (cefditoren pivoxil), or SPECTRACEF, and Balacet<sup>®</sup> 325 (propoxyphene 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 ALLERX, 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;

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.

In addition, 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 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 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, and its supply and marketing agreement with Pliva, Inc., or Pliva.

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 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 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;

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.

***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 selling Cornerstone's SPECTRACEF and the ALLERX family of products. As of June 30, 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 sell 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 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. Cornerstone's product candidates, such as its hydrocodone cough suppressant product candidates, that are modified or extended release formulations of existing products may not demonstrate sufficient additional clinical benefits to physicians to justify a higher price compared to immediate release generic equivalents within the same therapeutic class of API. 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 period of five years 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<sup>®</sup> (ceftibuten), Lupin Pharmaceuticals, Inc.'s Suprax<sup>®</sup> (cefixime) and generic formulations of Abbott Laboratories, Inc.'s Omnicef<sup>®</sup> (cefdinir), Pharmacia and Upjohn Company, Inc.'s Vantiv<sup>®</sup> (cefepodoxime), GlaxoSmithKline plc's Ceftin<sup>®</sup> (cefuroxime) and Bristol-Myers Squibb Company's Cefzil<sup>®</sup> (cefprozil); macrolides, such as generic formulations of Pfizer Inc.'s Zithromax<sup>®</sup> (azithromycin) and Abbott Laboratories, Inc.'s 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 Dose Pack Products* – prescription products, including first generation antihistamine and antihistamine combination products, such as Capellon Pharmaceuticals, Ltd.'s Rescon-M<sup>®</sup> (chlorpheniramine, methscopolamine and phenylephrine), Poly Pharmaceuticals, Inc.'s Poly Hist Fort<sup>®</sup> (chlorpheniramine, phenylephrine and pyrilamine) and Laser Pharmaceuticals, LLC's Daller<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 and APAP 500* – generic formulations of propoxyphene and acetaminophen, the active pharmaceutical ingredients in BALACET 325 and APAP 500, and many other drugs on the market or in development for the treatment of mild to moderate pain.

*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 polystirex), Wyeth's Robitussin-DM<sup>®</sup> (dextromethorphan and guaifenesin) and Procter & Gamble Company's Vicks Formula 4<sup>®</sup> Cough Relief (dextromethorphan, phenylephrine and chlorpheniramine); and prescription cough suppressants, such as Sciele Pharma, Inc.'s Rondec<sup>®</sup> DM Syrup (chlorpheniramine, phenylephrine and dextromethorphan) and Meda Pharmaceuticals Inc.'s Tussi-12<sup>®</sup> (carbetapentane, pyrilamine and phenylephrine).

Many of Cornerstone's competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than it does. These competitors also compete with Cornerstone in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in 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.



***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.

***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 cefditoren pivoxil, the API in SPECTRACEF. If SPECTRACEF does not achieve the level of sales Cornerstone anticipates, Cornerstone may not be able to use all of the cefditoren pivoxil it is required to purchase. Cornerstone is using its current inventory of cefditoren pivoxil for formulation, development and manufacture of the currently marketed SPECTRACEF product as well as the SPECTRACEF line extensions.

Cornerstone is subject to minimum purchase obligations under its manufacturing agreement with Bayer Healthcare, LLC, or Bayer, for the purchase of bulk tablets for the ALLERX product line. If there are changes to the market that negatively impact the demand for ALLERX, Cornerstone would be required to pay Bayer a variable amount 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 an 18-month shelf life, if demand does not meet or exceed Cornerstone's forecast over the next

12 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 and ALLERX-D contain pseudoephedrine and BALACET 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 its third-party manufacturers and packagers 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.

***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.

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

to a per claim deductible. 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.

## **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. Except for SPECTRACEF 400 mg, for which Cornerstone has submitted a supplemental new drug application, or sNDA, to the FDA, 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. 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, it 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 cannot predict whether it will encounter problems with any of its completed, ongoing 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 ongoing and 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 ongoing or 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 clinical 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.

As a result of these factors, 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 ongoing or 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, it may experience delays, incur additional costs and ultimately be unable to commercialize its product candidates.***

Depending upon the nature of the product candidate, obtaining regulatory approval for the sale of its product candidates may require Cornerstone and its collaborators to fund and conduct clinical trials to demonstrate the safety and efficacy of Cornerstone's product candidates in humans. Clinical testing is expensive, difficult to design and implement, uncertain as to outcome and, depending on the design of the trial, takes several years or more to complete. Clinical data is often susceptible to varying interpretations, and many companies that have believed their products

performed satisfactorily in clinical trials were nonetheless unable to obtain FDA approval for their product candidates. Similarly, even if clinical trials of a product candidate are successful in one indication, clinical trials of that product candidate for other indications may be unsuccessful. One or more of Cornerstone's clinical trials could fail at any stage of testing.

Cornerstone expects to submit an NDA to the FDA in 2009 for SPECTRACEF Suspension for use of this product candidate by children with pharyngitis or tonsillitis. TAP Pharmaceuticals, Inc., or TAP, conducted all of the preclinical studies and clinical trials of the oral suspension formulation of SPECTRACEF before



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

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

be delayed in obtaining marketing approval for its product candidates;

not be able to obtain marketing approval;

obtain approval for indications that are not as broad as intended; or

have the product removed from the market after obtaining marketing approval.

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

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

Cornerstone's product candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, the DEA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent Cornerstone from commercializing the product candidate. Cornerstone acquired the rights to most of its currently marketed products through two licensing transactions, one for ALLERX in February 2005 and the other for SPECTRACEF in October 2006, and 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 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. 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 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.

***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 ALLERX and some antispasmodic drugs like HYOMAX, are marketed under FDA enforcement policies established in connection with the FDA's Drug Efficacy Study Implementation, or DESI, program, which was established to determine the effectiveness of drug products approved before 1962. Prior to 1962, the FDCA required proof of safety but not efficacy for new drugs. Drugs that were not subject to applications approved between 1938 and 1962 were not subject to DESI review. For a period of time, the FDA permitted these drugs to remain on the market without approval. In 1984, the FDA created a program, known as the Prescription Drug Wrap-Up, also known as DESI II, to address these remaining unapproved drugs. Most of these drugs contain active pharmaceutical ingredients that were first marketed prior to 1938. The FDA asserts that all drugs subject to the Prescription Drug Wrap-Up are on the market illegally and are subject to FDA enforcement discretion because all prescription drugs must be the subject of an approved drug application. There are several narrow exceptions. For example, both the original statutory language of the FDCA and the amendments enacted in 1962 include provisions exempting specified drugs from the new drug requirements. The 1938 clause exempts drugs that were on the market prior to the passage of the FDCA in 1938 and that contain the same representations concerning the conditions of use as they did prior to passage of the FDCA. The 1962 amendments exempt, in specified circumstances, drugs that have the same composition and labeling as they had prior to the passage of the 1962 amendments. The FDA and the courts have interpreted these two exceptions very narrowly. The FDA has adopted a risk-based enforcement policy concerning these unapproved drugs. While all such drugs are considered to require FDA approval, FDA enforcement against such products as unapproved new drugs prioritizes products that pose potential safety risks, lack evidence of effectiveness, prevent patients from seeking effective therapies or are marketed fraudulently. In addition, the FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug requirements against all other drugs within that class that have not been so approved.

All ALLERX and HYOMAX brands 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 or require the removal of the ALLERX and HYOMAX products from the market, which would significantly reduce Cornerstone's revenue from product sales.

In addition, once 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. 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 ALLERX products be removed from the market immediately. In addition, 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. 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 HYOMAX 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. For example, after the FDA had approved Adams Respiratory Therapeutics, Inc.'s NDA for Mucine<sup>®</sup>, an extended-release guaifenesin product, the FDA directed in May 2007 that all other extended release guaifenesin products, including Cornerstone's Deconsal II product, be removed from the market within 180 days. Cornerstone's net sales of Deconsal II were \$177,000 in 2007 and \$1.2 million in 2006.

***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. 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.

***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 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 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.

***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 85 employees as of June 30, 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;

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.

### **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, including U.S. patent 6,843,372, or the '372 Patent, which Cornerstone believes covers ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30, have been challenged by third parties that have requested that the U.S. Patent and Trademark Office re-examine these patents. 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 200 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 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.

Because Cornerstone's products other than SPECTRACEF and product candidates other than the SPECTRACEF line extensions lack composition of matter protection for the API, 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 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 rights to most 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 third-party 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 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 has 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's single-source agreements include those relating to BALACET 325 and 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

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 attempting to sell the facility. 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.

***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 plans to rely significantly on third parties to market 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. For example, SJ Pharmaceuticals, LLC, or SJ Pharmaceuticals, is jointly promoting and marketing the ALLERX Dose Pack family and SPECTRACEF in specified sales territories in the United States, which expands Cornerstone's marketing reach with respect to those 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 Cornerstone's sales force. For example, in July 2007, Atley Pharmaceuticals began marketing 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 its 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 was 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 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 March 31, 2008, Cornerstone had approximately \$416,000 of cash and cash equivalents on hand and available borrowing capacity of \$3.25 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

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.

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. 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. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

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, it may be necessary to relinquish valuable rights to Cornerstone's 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 approximately \$669,000 in the quarter ended March 31, 2008 and \$571,000 in the year ended December 31, 2007. As of March 31, 2008, Cornerstone's accumulated deficit was \$12.4 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 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
- 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 achieve profitability. Cornerstone may continue to incur additional losses. Even if Cornerstone does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. Cornerstone's failure to become and remain profitable 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 these financial statements requires Cornerstone to make estimates and judgments that affect the reported amounts of its assets, liabilities, 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. Cornerstone cannot assure you, however, 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 its 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. Cornerstone has not demonstrated its ability to obtain regulatory approval of any product candidate or 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; and

unexpected product liability or intellectual property claims and lawsuits.

### **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 Relating to Cornerstone's Corporate Structure**

*Insiders have substantial control over Cornerstone and could delay or prevent a change in corporate control, including a transaction in which its stockholders could sell or exchange their shares for a premium.*

As of June 30, 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. 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 Cornerstone'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 Cornerstone's management and affairs. Accordingly, this concentration of ownership may harm the value of Cornerstone'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.

## **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.

*Critical Therapeutics and Cornerstone may not realize the benefits they expect from the merger.*

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 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.

The execution of these post-merger events will involve considerable risks and may not be successful. These risks include:

- the potential disruption of the combined company's ongoing business and distraction of its management;
- the potential strain on the combined company's financial and managerial controls and reporting systems and procedures;
- unanticipated expenses and potential delays related to integration of the operations, technology and other resources of the two companies;
- the impairment of relationships with employees, suppliers and customers as a result of any integration of new management personnel;
- 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.

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.

***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 profitability and reputation.

***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 June 30, 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 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 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.

## FORWARD-LOOKING STATEMENTS

This proxy statement/prospectus includes forward-looking statements within the meaning of Section 21E 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 of either Critical Therapeutics or Cornerstone, 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, will, would or other words that convey uncertainty 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 17 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.



## 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**

**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 290 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.

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 130. 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

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.

## THE MERGER

*This section and the section entitled "The Merger Agreement" beginning on page 115 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 297 of this proxy statement/prospectus.*

### 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. 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.

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.

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. Critical Therapeutics also prepared an electronic data room and granted access to that information to several companies, and was granted access to similar information by several companies. 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.

Beginning in September 2007, Critical Therapeutics engaged in substantive discussions with a privately held biotechnology company, or Company X. Beginning in October 2007, Critical Therapeutics engaged in substantive discussions with a privately held biotechnology company, or Company Y. Beginning in December 2007, Critical Therapeutics engaged in substantive discussions with a publicly traded biotechnology company, or Company Z. Beginning in February 2008, Critical Therapeutics engaged in substantive discussions with Cornerstone.

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. 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.

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.

During the fourth quarter of 2007 and the first quarter of 2008, sales of ZYFLO CR were lower than anticipated. In addition, in March 2008, Critical Therapeutics began to experience problems in the supply chain for ZYFLO CR. During this time, Critical Therapeutics cash position also continued to decrease. In addition, conditions in the national economy and the financial markets in particular continued to present challenges for life sciences companies seeking financing. These factors reinforced the view of Critical Therapeutics board of directors that concluding the strategic alternatives process as soon as practical was in the best interests of Critical Therapeutics stockholders.

On February 14, 2008, Critical Therapeutics board of directors held a meeting, also attended by members of Critical Therapeutics management and representatives of WilmerHale and Lazard, at which the board received an update on the strategic process, including information regarding the commercial, clinical and business operations of Company Z.

On February 15, 2008, Craig Collard, President, Chief Executive Officer and a director of Cornerstone, contacted by telephone Frank E. Thomas, then President, Chief Executive Officer and a director of Critical Therapeutics, to discuss the possibility of a strategic transaction between Cornerstone and Critical Therapeutics.

On February 20, 2008, Critical Therapeutics and Cornerstone executed a confidentiality agreement for the purpose of exchanging non-public information to facilitate discussions between the two companies. On or after February 20, 2008, Critical Therapeutics sent a detailed presentation regarding Critical Therapeutics via e-mail to representatives of Cornerstone.

On February 28, 2008, Thomas P. Kelly, Chief Financial Officer and Senior Vice President of Finance and Corporate Development of Critical Therapeutics, and Roger Heerman, Vice President of Sales and Marketing of Critical Therapeutics, held a telephone conference with Mr. Collard and Brian Dickson, M.D., Chief Medical Officer of Cornerstone. During this telephone conference, the parties made presentations to each other regarding their respective companies and their businesses.

On March 3, 2008, Cornerstone sent a detailed presentation regarding Cornerstone via e-mail to representatives of Critical Therapeutics and Lazard. Also on March 3, 2008, Mr. Collard e-mailed Mr. Thomas to inform him that Cornerstone was interested in continuing discussions regarding a transaction with Critical Therapeutics.

On March 4, 2008, Critical Therapeutics publicly announced that Mr. Thomas had informed Critical Therapeutics board of directors that he had resigned as a director effective March 2, 2008 and was resigning as President and Chief Executive Officer effective March 31, 2008, and that Trevor Phillips, Ph.D., Critical Therapeutics Senior Vice President of Operations and Chief Operating Officer, had been appointed as a director effective March 4, 2008 and would become President and Chief Executive Officer of Critical Therapeutics effective April 1, 2008.

In early March 2008, after many meetings and discussions between Critical Therapeutics and Company Z regarding the acquisition process, participating in a significant mutual due diligence review process and conducting negotiations regarding a definitive agreement, Company Z indicated that it had other business priorities and had decided not to move forward with a merger with Critical Therapeutics.



On March 7, 2008, Mr. Collard, Dr. Dickson and Alastair McEwan, Chairman of the board of directors of Cornerstone, traveled to Critical Therapeutics' offices in Lexington, Massachusetts and met with Dr. Phillips, Mr. Thomas, Mr. Kelly, Mr. Heerman and Roberta Tucker, Senior Vice President of Regulatory Affairs of Critical Therapeutics. During this meeting, the managements of both Cornerstone and Critical Therapeutics made presentations regarding their respective companies and their businesses. Representatives of Jefferies & Company, Inc., or Jefferies, Cornerstone's financial advisor, were also present at this meeting.

Following the meeting on March 7, 2008, Critical Therapeutics and Cornerstone continued mutual due diligence on the business, assets and liabilities of each company, including telephone conferences and review of information contained in each company's electronic dataroom. In addition, representatives of both companies' management teams and their respective legal and financial advisors conducted numerous discussions regarding the potential terms of a transaction.

On March 12, 2008, Dr. Phillips, Mr. Kelly, Mr. Heerman and Mr. Thomas held a telephone conference call with Mr. Collard, Mr. McEwan and a representative of Jefferies regarding the proposed transaction with Cornerstone and the acquisition process in general.

On March 13, 2008, representatives of the parties' management and financial advisors held a further telephone conference to discuss the proposed transaction with Cornerstone, potential deal terms and the acquisition process in general.

On March 17, 2008, Cornerstone sent a letter via e-mail to Critical Therapeutics reflecting a non-binding expression of interest regarding a potential merger with Critical Therapeutics in which Critical Therapeutics would issue common stock to Cornerstone stockholders for all of Cornerstone's equity capital. In this letter, Cornerstone preliminarily proposed a transaction in which Critical Therapeutics' stockholders would hold 34% of the combined company, based on Critical Therapeutics having a cash balance at closing of at least \$20 million.

Critical Therapeutics' board of directors met on March 20, 2008 in Cambridge, Massachusetts and by teleconference, together with members of Critical Therapeutics' management and representatives of WilmerHale and Lazard. At this meeting, representatives of Cornerstone made a presentation to Critical Therapeutics' board regarding a possible strategic transaction between Cornerstone and Critical Therapeutics and related matters. Following this presentation, Cornerstone's representatives departed the meeting. Critical Therapeutics' board then continued to discuss a potential strategic transaction with Cornerstone. As part of this discussion, Lazard provided an update on the status of the strategic review process and potential transaction with Cornerstone, 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.

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

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. Critical Therapeutics' board determined that the stage of discussions with Cornerstone justified additional mutual due diligence and the negotiation of definitive documentation regarding a merger between the two companies.

On April 14, 2008, Critical Therapeutics' board of directors met by telephone conference. Mr. Kelly and Scott B. Townsend, Senior Vice President of Legal Affairs, General Counsel and Secretary of Critical Therapeutics, participated in the meeting. Dr. Phillips and Mr. Kelly provided the board with an update on the status of discussions with Cornerstone regarding a potential transaction, the status of a draft definitive merger agreement with Cornerstone and the status of financial and accounting due diligence on Cornerstone. Dr. Phillips then provided Critical Therapeutics' board with an update regarding the status of discussions with other potential candidates for a strategic transaction.

On April 15, 2008, Critical Therapeutics provided Cornerstone with a first draft of a definitive merger agreement. Between April 15, 2008 and April 30, 2008, representatives of Critical Therapeutics and

Cornerstone negotiated the terms of the proposed merger agreement. Negotiations focused on, among other matters, the conditions to closing, post-signing operating covenants, termination rights, the amount of termination fees, required levels of cash, debt and working capital, representations and warranties, and the timing of the re-audit of Cornerstone's financial statements.

On April 18, 2008, Dr. Phillips and Mr. Collard met by telephone conference to discuss various aspects of the proposed transaction, including operational and business strategy issues.

On April 24, 2008, Critical Therapeutics' board of directors held a meeting by telephone conference. Also present at this meeting were members of Critical Therapeutics' management and representatives of WilmerHale and Lazard. At this meeting, among other things, Dr. Phillips provided an update on and led a discussion regarding the potential transaction with Cornerstone, including the status of financial, tax and accounting due diligence, and the status of negotiations regarding a draft definitive agreement with Cornerstone. After discussion, the board determined to proceed with the final negotiations of a definitive agreement with Cornerstone.

Following Critical Therapeutics' board meeting on April 24, 2008, representatives of Critical Therapeutics, WilmerHale, Lazard, Cornerstone, Jefferies and Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., or Smith Anderson, Cornerstone's outside legal counsel, continued negotiation of the definitive agreement. Preliminary agreement was reached on a number of matters, including agreement that the exchange ratio in the merger would provide that Critical Therapeutics' stockholders would hold 30% of the combined company but without any condition 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;

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;

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.

**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.

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.**

#### **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;

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 under specified circumstances;

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 relisting 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 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.**

#### **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 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 and other conditions as in effect on, and the information made available to Lazard as of, May 1, 2008, the date of its opinion. Lazard assumes no responsibility for updating or revising its opinion based on circumstances or events occurring after the date of the opinion.**

In connection with its opinion, Lazard:

reviewed the financial terms and conditions of the merger agreement;

analyzed certain publicly available historical business and financial information relating to Critical Therapeutics and certain historical business and financial information relating to Cornerstone;

reviewed various financial forecasts and other data provided to Lazard by Critical Therapeutics relating to Critical Therapeutics' business and financial forecasts and other data provided to Lazard by Cornerstone, as adjusted by Critical Therapeutics, relating to Cornerstone's business;

held discussions with members of the senior managements of Critical Therapeutics and Cornerstone with respect to the businesses and prospects of Critical Therapeutics and Cornerstone, respectively;

reviewed public information with respect to certain other companies in lines of business Lazard believed to be generally relevant in evaluating the businesses of Critical Therapeutics and Cornerstone, respectively;

reviewed historical stock prices and trading volumes of Critical Therapeutics common stock; and

conducted such other financial studies, analyses and investigations as Lazard deemed appropriate.

Lazard assumed and relied upon the accuracy and completeness of the foregoing information, without independent verification of such information. Lazard did not conduct any independent valuation or appraisal of any of the assets or liabilities (contingent or otherwise) of Critical Therapeutics or Cornerstone or concerning the solvency or fair value of Critical Therapeutics or Cornerstone, and Lazard was not furnished with such valuation or appraisal. With respect to the financial forecasts that Lazard reviewed (including, in the case of Cornerstone, adjustments to such forecasts by Critical Therapeutics), Lazard assumed, with Critical Therapeutics' consent, that they were reasonably prepared on bases reflecting the best currently available estimates and judgments of the managements of Critical Therapeutics and Cornerstone, as the case may be, as to the future financial performance of Critical Therapeutics and Cornerstone. Lazard assumed no responsibility for and expressed no view as to such forecasts or the assumptions on which they were based. Lazard relied on the assessments of Critical Therapeutics' management as to the validity of, and risks associated with, the products and product candidates of Critical Therapeutics and Cornerstone (including, without limitation, the timing and probability of successful development, testing and marketing, and of approval by appropriate governmental authorities, of such products and product candidates). Lazard was advised by representatives of Critical Therapeutics and Cornerstone that a new audit of the historical financial statements of Cornerstone would be performed, and Lazard assumed, with Critical Therapeutics' consent, that such audited historical financial statements, when completed, would not vary materially from the audited historical financial statements of Cornerstone provided to Lazard by Cornerstone.

In rendering its opinion, Lazard assumed, with Critical Therapeutics' consent, that the merger and related transactions (including, without limitation, the reverse stock split and the contemplated exchange or conversion of the Carolina Note into shares of Cornerstone common stock as a condition to the closing of the merger) would be consummated on the terms described in the merger agreement, without any waiver or modification of any material terms or conditions. Lazard also assumed, with Critical Therapeutics' consent, that obtaining the necessary regulatory or third party approvals and consents for the merger or any related transaction would not have an adverse effect on Critical Therapeutics, Cornerstone or the merger. Lazard further assumed, with Critical Therapeutics' consent, that the representations and warranties of Critical Therapeutics and Cornerstone contained in the merger agreement were true and complete and that the merger would qualify for U.S. federal income tax purposes as a reorganization within the meaning of Section 368(a) of the Code. Lazard did not express any opinion as to any tax or other consequences that might result from the merger or any related transaction, nor did Lazard's opinion address any legal, tax, regulatory or accounting matters, as to which Lazard understood that Critical Therapeutics obtained such advice as it deemed necessary from qualified professionals. Lazard expressed no view or opinion as to any terms or other aspects or implications of the merger (other than the exchange ratio to the extent expressly specified in its opinion) or any related transaction, including, without limitation, the form or structure of the merger, any adjustment to the exchange ratio resulting from the reverse stock split, any other aspect or implication of the reverse stock split or any agreements or arrangements entered into in connection with, or otherwise contemplated by, the merger. In addition, Lazard expressed no view or opinion as to the fairness of the amount or nature of, or any other aspects relating to, the compensation to any officers, directors or employees of any parties to the merger, or class of such persons, relative to the exchange ratio or otherwise. Further, Lazard did not express any opinion as to the price at which shares of Critical Therapeutics' common stock would trade at any time subsequent to the announcement of the merger. Except as described above, Critical Therapeutics imposed no other instructions or limitations on Lazard with respect to the investigations made or the procedures followed by Lazard in rendering its opinion. The issuance of Lazard's opinion was approved by an authorized committee of Lazard.

The following is a brief summary of the material financial and comparative analyses that Lazard deemed to be appropriate for this type of transaction and that were reviewed with Critical Therapeutics' board of directors by Lazard in connection with rendering its opinion. The summary of Lazard's analyses described below is not a complete

description of the analyses underlying Lazard's opinion. The preparation of a financial opinion is a complex analytical process involving various determinations as to the most appropriate and relevant methods of financial analyses and the application of those methods to the particular circumstances, and, therefore, is

not readily susceptible to summary description. In arriving at its opinion, Lazard considered the results of all of the analyses and did not draw, in isolation, conclusions from or with regard to any factor or analysis considered by it. Rather, Lazard made its determination as to fairness on the basis of its experience and professional judgment after considering the results of all of the analyses.

In its analyses, Lazard considered industry performance, general business, economic, market and financial conditions and other matters, many of which are beyond the control of Critical Therapeutics and Cornerstone. No company used in Lazard's analyses is identical to Cornerstone or Critical Therapeutics, and an evaluation of the results of those analyses is not entirely mathematical. Rather, the analyses involve complex considerations and judgments concerning financial and operating characteristics and other factors that could affect the public trading or other values of the companies analyzed. The estimates contained in Lazard's analyses and the ranges of valuations resulting from any particular analysis are not necessarily indicative of actual values or predictive of future results or values, which may be significantly more or less favorable than those suggested by the analyses. In addition, analyses relating to the value of businesses or securities do not purport to be appraisals or to reflect the prices at which businesses or securities actually may be sold. Accordingly, the estimates used in, and the results derived from, Lazard's analyses are inherently subject to substantial uncertainty.

The financial analyses summarized below include information presented in tabular format. **In order to fully understand Lazard's financial analyses, the tables must be read together with the text of each summary. The tables alone do not constitute a complete description of the financial analyses. Considering the data in the tables below without considering the full narrative description of the financial analyses, including the methodologies and assumptions underlying the analyses, could create a misleading or incomplete view of Lazard's financial analyses.** For purposes of the analyses summarized below, the term "merger exchange ratio" refers to the implied exchange ratio of 2.9946x, calculated as set forth in the merger agreement based on the product of 2.3333 multiplied by the quotient of 43,479,198 divided by the estimate of Cornerstone's management of the fully diluted shares of Cornerstone common stock as of April 30, 2008 and before adjustment for the reverse stock split of Critical Therapeutics' common stock to occur in connection with the merger. For purposes of the "Cornerstone Financial Analyses" summarized below, the term "implied per share merger consideration" refers to the implied per share value of \$1.86 based on a merger exchange ratio of 2.9946x and Critical Therapeutics' closing stock price on April 30, 2008 of \$0.62 per share.

### ***Cornerstone Financial Analyses***

#### ***Discounted Cash Flow Analysis***

Lazard performed a discounted cash flow analysis of Cornerstone to calculate the estimated present value as of March 31, 2008 of the standalone unlevered, after-tax free cash flows that Cornerstone was forecasted to generate 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%. This analysis indicated the following implied per share equity reference range for Cornerstone, as compared to the implied per share merger consideration:

**Implied Per Share Equity  
Reference Range for Cornerstone**

**Implied Per Share  
Merger Consideration**

\$4.50 - \$5.50

\$1.86

*Selected Publicly Traded Companies Analysis*

Lazard reviewed publicly available financial information for the following six publicly traded mid-stage specialty pharmaceutical companies:

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, 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 and estimated EBITDA for calendar years 2008, 2009 and 2010 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% to reflect the fact that 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

***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%. 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 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 derived from the selected companies to corresponding financial data of Critical Therapeutics. Estimated financial data of the selected companies were based on publicly available research analysts estimates and other publicly available information. Estimated financial data of Critical Therapeutics were based on internal estimates of Critical Therapeutics' s management with respect to Critical Therapeutics' product and product candidates, probability-weighted, in the case of estimated financial results attributable to a product candidate, to reflect management' s assessments as to the likelihood of obtaining regulatory approval to commercialize the product candidate. This analysis indicated the following implied per share equity reference range for Critical Therapeutics based on the financial metrics referred to above, as compared to the per share closing price of Critical Therapeutics common stock on April 30, 2008:

**Implied Per Share Equity  
Reference Range for Critical Therapeutics**

\$1.20 - \$1.55

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

\$0.62

***Implied Pro Forma Ownership Analyses***

Using the implied equity reference ranges for Cornerstone and Critical Therapeutics derived from the Discounted Cash Flow Analysis and Selected Publicly Traded Companies Analysis described above, Lazard derived an implied equity ownership percentage for Cornerstone' s stockholders in the combined company upon consummation of the merger. This analysis indicated the following range of implied pro forma equity ownership percentages for Cornerstone' s stockholders, as compared to the pro forma equity ownership percentage for Cornerstone' s stockholders implied by the merger exchange ratio:

**Cornerstone Implied Pro Forma Equity Ownership  
Percentage Reference Ranges**

<b>Discounted Cash Flow Analysis</b>	<b>Selected Publicly Traded Companies Analysis</b>	<b>Cornerstone Pro Forma Equity Ownership Percentage Implied by Merger Exchange Ratio</b>
64% - 77%	60% - 73%	70.0%

***Miscellaneous***

In connection with Lazard's services as Critical Therapeutics' financial advisor, Critical Therapeutics has agreed to pay to Lazard a customary fee, a portion of which was payable upon the rendering of Lazard's opinion and a substantial portion of which is contingent upon the closing of the merger. Critical Therapeutics also has agreed to reimburse Lazard for its reasonable expenses, including reasonable attorneys' fees, and to indemnify Lazard and certain related parties against certain liabilities that may arise out of the rendering of its advice, including certain liabilities under U.S. federal securities laws.

Lazard, as part of its investment banking business, is continually engaged in the valuation of businesses and their securities in connection with mergers and acquisitions, negotiated underwritings, secondary distributions of listed and unlisted securities, private placements, leveraged buyouts, and valuations for estate, corporate and other purposes. Lazard in the past has provided and in the future may provide investment banking services to Critical Therapeutics, for which Lazard has received and may receive compensation, including having acted as exclusive financial advisor to Critical Therapeutics in connection with a licensing transaction in 2007. In addition, Lazard Capital Markets LLC, or LCM, an entity indirectly owned in large part by managing directors of Lazard, acted as sole placement agent in connection with an equity offering of Critical Therapeutics in 2006, for which LCM was paid a customary fee, a portion of which was paid by LCM to Lazard as a referral fee. In the ordinary course of their respective businesses, affiliates of Lazard and LCM may actively trade securities of Critical Therapeutics for their own accounts and for the accounts of their customers and, accordingly, may at any time hold a long or short position in such securities.

Lazard is an internationally recognized investment banking firm providing a full range of financial advisory and securities services. Lazard was selected to act as Critical Therapeutics' financial advisor because of its qualifications, experience and reputation in investment banking and mergers and acquisitions and its familiarity with Critical Therapeutics.

Lazard prepared the above analyses for the purpose of providing an opinion to Critical Therapeutics' board of directors as to the fairness, from a financial point of view, to Critical Therapeutics of the exchange ratio. Lazard did not recommend any specific consideration to Critical Therapeutics' board of directors or that any given consideration constituted the only appropriate consideration for the merger.

Lazard's opinion and analyses were only one of many factors taken into consideration by Critical Therapeutics' board of directors in its evaluation of the merger. Consequently, the analyses described above should not be viewed as determinative of the views of Critical Therapeutics' board of directors or Critical Therapeutics' management with respect to the exchange ratio or as to whether Critical Therapeutics' board of directors would have been willing to determine that a different consideration was fair.

### **Interests of Critical Therapeutics' Directors and Executive Officers in the Merger**

In considering the recommendation of Critical Therapeutics' board of directors with respect to issuing shares of Critical Therapeutics' common stock as contemplated by the merger agreement and the other matters to be acted upon by Critical Therapeutics' stockholders at the special meeting, Critical Therapeutics' stockholders should be aware that members of the board of directors and executive officers of Critical Therapeutics have interests in the merger that are different from, or in addition to, the interests of Critical Therapeutics' stockholders. Critical Therapeutics' and Cornerstone's boards of directors were aware of these potential conflicts of interest and considered them, among other matters, in reaching their respective decisions to approve the merger agreement and the merger, in the case of Cornerstone's board of directors, to recommend that Cornerstone's stockholders vote to adopt the merger agreement, and, in the case of Critical Therapeutics' board of directors, to recommend that Critical Therapeutics' stockholders vote to approve the issuance of Critical Therapeutics' common stock in connection with the merger and the other matters to be acted upon by Critical Therapeutics' stockholders at the special meeting.

### ***Ownership Interests***

As of June 30, 2008, all directors and executive officers of Critical Therapeutics, together with their affiliates, beneficially owned approximately 23.0% of the shares of Critical Therapeutics' common stock. The affirmative vote of the holders of a majority of the shares of Critical Therapeutics' common stock present in person or represented by proxy and voting on such matter at the special meeting is required for approval of Proposal 1 and Proposal 4. The affirmative vote of holders of a majority of the outstanding shares of Critical Therapeutics' common stock as of the

record date for the special meeting is required for approval of Proposal 2 and Proposal 3.

### ***Employment Agreements***

Critical Therapeutics has entered into employment agreements with each of its executive officers. On December 21, 2004, Critical Therapeutics entered into employment agreements with Dr. Phillips and Mr. Townsend. On June 26, 2006, Critical Therapeutics entered into an employment agreement with Jeffrey E. Young, Vice President of Finance, Chief Accounting Officer and Treasurer. On August 21, 2007, Critical Therapeutics entered into an employment agreement with Mr. Kelly. In November 2007, Critical Therapeutics entered into amended and restated employment agreements with Dr. Phillips, Mr. Townsend and Mr. Young. In April 2008, Critical Therapeutics entered into a further amended and restated employment agreement with Dr. Phillips in connection with his appointment as President and Chief Executive Officer.

Each of the employment agreements with its current executive officers, other than with Mr. Kelly, has an initial term that extends through December 31, 2009. Mr. Kelly's employment agreement has an initial term that extends through December 31, 2008. Each of these employment agreements automatically extends for an additional one-year term after the initial term unless either Critical Therapeutics or the executive officer gives 90-days prior notice.

Under the employment agreements, each executive officer is paid a base salary and is eligible for an annual cash bonus of a specified percentage of his annual base salary and an annual equity award. The employment agreements provide for an annual base salary of \$330,000 for Dr. Phillips, \$279,500 for Mr. Kelly, \$275,000 for Mr. Townsend and \$202,800 for Mr. Young and an annual target cash bonus as a percentage of base salary of 40% for Dr. Phillips, 30% for Mr. Kelly, 30% for Mr. Townsend and 30% for Mr. Young.

Each employment agreement with the current executive officers of Critical Therapeutics provides that if Critical Therapeutics terminates the executive officer's employment other than for cause or if the executive officer terminates his employment for good reason, in each case as those terms are defined in his employment agreement, then Critical Therapeutics is obligated to provide the following to the executive officer, provided such person executes and delivers to Critical Therapeutics a severance agreement and release drafted by and satisfactory to counsel to Critical Therapeutics:

- a lump sum payment equal to his annual base salary in effect at that time for each executive officer other than Dr. Phillips, and a lump sum payment equal to 1.25 times his annual base salary in effect at that time for Dr. Phillips;

- monthly payments in the amount of 100% of the monthly COBRA premiums for continued health and dental coverage for the executive officer and his dependents for each executive officer other than Mr. Kelly, and 80% of the monthly COBRA premiums for continued health and dental coverage for Mr. Kelly and his dependents, and 100% of the amount of the monthly premiums paid by Critical Therapeutics for life insurance and disability insurance for the executive officer until the earlier of one year, or in the case of Dr. Phillips 15 months, after termination or the last day of the first month when such officer is eligible for benefits through other employment;

- a pro rata payment of his target cash bonus in effect in the year of termination; and

- accelerated vesting of 50% of his outstanding unvested stock options and restricted stock.

Immediately upon a change of control of Critical Therapeutics, as defined in his employment agreement, each executive officer is entitled to accelerated vesting of 50% of all his outstanding unvested stock options and restricted stock. In addition, Dr. Phillips is entitled to receive a one-time lump sum payment of \$175,000 upon a change of control.

If Critical Therapeutics terminates the executive officer's employment other than for cause or if the executive officer terminates his employment for good reason during the period from three months before until one year after the occurrence of a change of control, then Critical Therapeutics is obligated to provide

the following to the executive officer, provided such person executes and delivers to Critical Therapeutics a severance agreement and release drafted by and satisfactory to counsel to Critical Therapeutics:

lump sum payment equal to his annual base salary in effect at that time for each executive officer other than Dr. Phillips, and a lump sum payment equal to 1.5 times his annual base salary in effect at that time for Dr. Phillips;

monthly payments in the amount of 100% of the monthly COBRA premiums for continued health and dental coverage for the executive officer and his dependents for each executive officer other than Mr. Kelly and 80% of the monthly COBRA premiums for continued health and dental coverage for Mr. Kelly and his dependents, and 100% of the amount of the monthly premiums paid by Critical Therapeutics for life insurance and disability insurance for the executive officer until the earlier of one year, or in the case of Dr. Phillips 18 months, after termination or the last day of the first month when such officer is eligible for benefits through other employment;

a pro rata payment of his target cash bonus in effect in the year of termination;

accelerated vesting of 100% of his outstanding unvested stock options and restricted stock; and

up to three months of outplacement services.

Upon voluntary resignation, each executive officer is entitled to a pro rata payment of his annual bonus from the previous year provided that the executive officer gives 90-days prior written notice of resignation and executes a release of Critical Therapeutics.

Each executive officer has agreed not to compete with Critical Therapeutics during his employment with Critical Therapeutics and for a one-year period after termination of employment by Critical Therapeutics for any reason or after a change of control of Critical Therapeutics. In the event of a breach of this non-competition obligation, Critical Therapeutics will be entitled to injunctive relief in addition to any other remedies it might have, and the executive will continue to be held to the obligation until the requisite time period has passed without any violation. Each executive officer has also agreed not to disclose any confidential information obtained during his employment. The severance agreements and releases used by Critical Therapeutics typically contain provisions, whereby a departing executive reaffirms these obligations, and non-disparagement clauses of perpetual duration, compliance with which is a condition to the receipt of payments.

#### ***Cash Bonus Awards Upon a Change in Control***

On July 16, 2008, based on the recommendation of the compensation committee, Critical Therapeutics board of directors established a bonus program for Critical Therapeutics executive officers providing for Critical Therapeutics to pay cash bonuses to its executive officers, other than Dr. Phillips, who remain employed with Critical Therapeutics and satisfactorily perform their job duties, as determined by Critical Therapeutics, upon the consummation of the merger or any other change in control of Critical Therapeutics, as defined in Critical Therapeutics 2004 Stock Incentive Plan, as amended. This cash bonus also would be payable if Critical Therapeutics terminates an executive officer's employment without cause, as defined in his employment agreement, within 28 days before the occurrence of a change in control, provided the executive officer executes and delivers to Critical Therapeutics a severance agreement and release drafted by and satisfactory to Critical Therapeutics. These cash bonuses are in addition to compensation and benefits otherwise payable to these executive officers under their employment agreements. Under this bonus program, the executive officers listed below are entitled to the following bonus amounts:

<b>Name</b>	<b>Cash Bonus Amount</b>
Thomas P. Kelly	\$ 45,000
Scott B. Townsend, Esq.	50,000
Jeffrey E. Young	35,000



As discussed above, pursuant to the terms of his employment agreement, Dr. Phillips is separately entitled to receive a lump sum payment of \$175,000 upon a change in control of Critical Therapeutics, as defined in his employment agreement.

***Summary of Potential Payments in Connection with the Merger***

Promptly following the effective time of the merger, the executive management team of the combined company is expected to be composed primarily of current Cornerstone executives. Accordingly, it is contemplated that Critical Therapeutics executive officers will be entitled to payments in connection with the consummation of the merger, which constitutes a change in control under each executive's employment agreement and Critical Therapeutics 2004 Stock Incentive Plan, as amended.

The following table sets forth information regarding payments and benefits that each executive officer of Critical Therapeutics is expected to receive in connection with the consummation of the merger pursuant to the terms of his employment agreement, assuming that the merger had been consummated on June 30, 2008.

Name	Immediately Upon a Change of Control			Termination in Connection with a Change of Control		
	Cash Payment	Accelerated Vesting(1)	Accelerated Vesting(2)	Cash Payments(3)	Value of Accelerated Vesting(4)	Accelerated Vesting(2)
Trevor Phillips, Ph.D.	\$ 175,000		\$ 7,841	\$ 727,750	\$ 34,649	\$ 15,683
Thomas P. Kelly	45,000		13,690	366,425	21,145	27,380
Scott B. Townsend, Esq.	50,000		11,227	366,250	26,375	22,454
Jeffrey E. Young	35,000		4,769	268,220	25,981	9,539

- (1) The amounts in this column are calculated based on the difference between \$0.37, the closing market price per share of Critical Therapeutics common stock on June 30, 2008, and the exercise price per share of the options subject to accelerated vesting. All options subject to accelerated vesting have an exercise price greater than \$0.37.
- (2) The amounts in this column are calculated by multiplying the number of shares subject to accelerated vesting by \$0.37, the closing market price per share of Critical Therapeutics common stock on June 30, 2008.
- (3) The amounts in this column reflect (i) a lump sum payment equal to annual base salary in effect on June 30, 2008, or in the case of Dr. Phillips, a lump sum payment equal to 1.5 times annual base salary in effect on June 30, 2008, and (ii) a pro rata payment of the target cash bonus for 2008 for the executive officer. The amount for Dr. Phillips includes the \$175,000 payment that he would be entitled to receive under his employment agreement upon the consummation of a change in control. The amount for each other executive officer includes the payment that such executive officer would be entitled to receive under the change in control cash bonus program.
- (4)

The amounts in this column reflect 12 monthly payments in the amount of (i) 100% of the monthly COBRA premiums for continued health and dental coverage for the executive officer and his dependents, or 80% in the case of Mr. Kelly, and (ii) 100% of the amount of life insurance and disability insurance for the executive officer in the month prior to termination for 12 months, or 18 months in the case of Dr. Phillips, if Critical Therapeutics terminates his employment other than for cause or if he terminates his employment for good reason during the period from three months before until one year after the occurrence of a change of control. In addition, the amounts in this column include \$10,000, which is an estimate of the fair market value of up to three months of outplacement services that would be provided to such executives if Critical Therapeutics terminates the executive's employment other than for cause or if an executive terminates his employment for good reason during the period from three months before until one year after the occurrence of a change of control.

### ***Director Stock Option Agreements***

Critical Therapeutics' directors Jean George and Richard W. Dugan are parties to stock option agreements with Critical Therapeutics that provide for accelerated vesting of the stock options granted pursuant to such agreements upon a change of control of Critical Therapeutics. All stock options subject to accelerated vesting have an exercise price that is greater than \$0.37, the closing market price per share of Critical Therapeutics' common stock on June 30, 2008.

### ***Indemnification of Officers and Directors***

The merger agreement provides that, for a period of six years following the effective time of the merger, Critical Therapeutics will, to the fullest extent permitted by law, indemnify and hold harmless each present and former director and officer of Critical Therapeutics against any costs or expenses (including attorneys' fees), judgments, fines, losses, claims, damages, liabilities or amounts paid in settlement incurred in connection with any claim, action, suit, proceedings or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to matters existing or occurring at or prior to the effective time of the merger, whether asserted or claimed prior to, at or after the effective time of the merger, to the fullest extent that Critical Therapeutics or one of its subsidiaries, as the case may be, would have been permitted under Delaware law and its certificate of incorporation or bylaws.

The merger agreement also provides that, for a period of six years following the effective time of the merger, Critical Therapeutics will maintain in effect a directors' and officers' liability insurance policy covering the directors and officers of Critical Therapeutics, with coverage in amount and scope at least as favorable as the coverage under Critical Therapeutics' existing policy as of the time the merger becomes effective. If the annual premiums payable for such insurance coverage exceed 150% of the current annual premiums paid by Critical Therapeutics for its existing policy, Critical Therapeutics will provide the maximum coverage that will then be available at an annual premium equal to 150% of such rate.

### ***Interests of Cornerstone's Directors and Executive Officers in the Merger***

Members of the board of directors and executive officers of Cornerstone may have interests in the merger that are different from, or are in addition to, the interests of Cornerstone's stockholders generally. These interests generally include, among other things, the potential for such persons to occupy positions as officers or directors of the combined company and the potential benefits under employment or severance arrangements as a result of the merger. The Cornerstone board of directors was aware of these interests and considered them, among other matters, in approving the merger agreement and in determining to recommend that Cornerstone's stockholders vote to approve and adopt the merger agreement.

### ***Board of Directors and Management***

Craig A. Collard is the Chief Executive Officer and a member of the board of directors of Cornerstone and, upon closing of the merger, Mr. Collard will become the President, Chief Executive Officer and a director of the combined company. Mr. Collard participated in the negotiation and approval of the terms of the merger on behalf of Cornerstone.

Following the merger, in addition to Mr. Collard, certain other directors and members of the senior management of Cornerstone will assume new positions with the combined company. Alastair McEwan is the Chairman of Cornerstone and, upon closing of the merger, will become a director of the combined company. Chenyqua Baldwin is the Vice President of Finance of Cornerstone and, upon closing of the merger, will become the Chief Accounting Officer, Controller and Vice President of Finance of the combined company. Brian Dickson, M.D. is the Chief

Medical Officer of Cornerstone and, upon the closing of the merger, he will hold the same position in the combined company. George Esgro is the Vice President of Sales and Marketing of Cornerstone and, upon the closing of the merger, he will hold the same position in the combined company. Steven M. Lutz is the Executive Vice President of Commercial Operations of Cornerstone and, upon closing of the merger, Mr. Lutz will become the Executive Vice President of Manufacturing and Trade in the combined company. Mr. McEwan, Ms. Baldwin, Dr. Dickson, Mr. Esgro and Mr. Lutz participated in the

negotiation of the terms of the merger. For a more complete description of the management of the combined company after the merger, please see the section *Management of the Combined Company After the Merger* beginning on page 256 of this proxy statement/prospectus.

### *Ownership Interests*

As of June 30, 2008, all directors and executive officers of Cornerstone, together with their associates, held interests in 18,295,000 shares of Cornerstone's common stock representing approximately 75.9% of Cornerstone's issued and outstanding common stock as of such date, including 13,450,000 shares owned by Cornerstone Biopharma Holdings, Ltd., an entity which is wholly-owned by Mr. Collard, and 1,250,000 shares owned by the Craig Collard Irrevocable Trust, a trust in which Mr. Collard has a substantial beneficial interest. For a more complete description of the ownership interests of the executive officers and directors of Cornerstone, please see the section entitled *Principal Stockholders of Cornerstone* beginning on page 293 of this proxy statement/prospectus.

### *Stock Options*

Under the terms of the merger agreement, at the effective time of the merger, each outstanding option to purchase shares of Cornerstone common stock, whether vested or unvested, will be assumed by Critical Therapeutics and will become an option to acquire, on the same terms and conditions as were applicable under the stock option agreement by which such option is evidenced and the stock option plan under which such option was issued, if any, shares of Critical Therapeutics' common stock. The number of shares of Critical Therapeutics' common stock subject to each assumed option will be determined by multiplying the number of shares of Cornerstone common stock that was subject to each option prior to the effective time of the merger by an exchange ratio determined pursuant to the merger agreement, and rounding that result down to the nearest whole number of shares of Critical Therapeutics' common stock. The per share exercise price for the assumed options will be determined by dividing the per share exercise price of the Cornerstone common stock subject to each option as in effect immediately prior to the effective time of the merger by the exchange ratio and rounding that result up to the nearest whole cent. The exact exchange ratio per share of Cornerstone's common stock will be based in part on the number of shares of Cornerstone's common stock outstanding on a fully diluted basis immediately prior to the effective time of the merger and will not be calculated until that time. For a more complete description of the merger, please see the section entitled *The Merger Agreement* beginning on page 115 of this proxy statement/prospectus.

The table below sets forth, as of June 30, 2008, information with respect to options held by each of Cornerstone's current executive officers and directors:

<b>Name</b>	<b>Total Options Held</b>	<b>Vested</b>	<b>Unvested</b>	<b>Weighted Average Exercise Price Per Share</b>
Craig A. Collard	1,050,000	300,000	750,000	\$ 0.40
Chenyqua Baldwin	840,000	242,500	597,500	0.39
Brian Dickson, M.D.	1,500,000	631,250	868,750	0.26
George Esgro(1)				
Steven M. Lutz	925,000	281,250	643,750	0.36
Alastair McEwan	1,500,000	1,035,000	465,000	0.21

- (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.

### ***Noteholder Agreement with Carolina Pharmaceuticals***

In April 2004, Cornerstone entered into the Carolina Note, an unsecured loan agreement with Carolina Pharmaceuticals, whereby Cornerstone could borrow up to \$15.0 million at 10% interest for five years. Because Mr. Collard owns over 50% of the voting shares of Carolina Pharmaceuticals, he is a control person of Carolina Pharmaceuticals. Cornerstone borrowed \$13.0 million under the Carolina Note in April 2004. In June 2006, Cornerstone entered into a note amendment and waiver agreement that provided for the offset of approximately \$3.6 million in principal and \$1.8 million in accrued interest outstanding under the Carolina Note against equal amounts due to Cornerstone from Cornerstone Biopharma Holdings, Ltd. and Carolina Pharmaceuticals. The amounts due to Cornerstone primarily resulted from the 2005 Adams litigation settlement. As of December 31, 2007 and 2006, approximately \$9.4 million in principal was outstanding under the Carolina Note plus approximately \$549,000 and \$1.5 million in accrued interest, respectively. On April 11, 2008, Cornerstone made a principal payment of \$460,000 on the Carolina Note. The outstanding principal and accrued interest are due in 2009. At June 30, 2008, the outstanding principal amount of the Carolina Note was approximately \$9.0 million.

Carolina Pharmaceuticals, which is the holder of the Carolina Note, has entered into an agreement that provides, among other things, for the exchange or conversion of the outstanding principal amount of the Carolina Note into shares of Cornerstone's common stock prior to the effective time of the merger and for the same voting and lock-up provisions provided pursuant to the agreements entered into by Cornerstone's other stockholders.

### ***Employment and Related Agreements***

Cornerstone is party to employment agreements with its executive officers. These agreements provide that the executive officer is entitled to minimum annual base salary, an annual bonus, severance, and certain health, retirement, and other benefits. The material terms of these agreements have been summarized in the section Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table beginning on page 265 of this proxy statement/prospectus. The individuals who are parties to these agreements, as well as their positions and annual base salaries, are as follows: (i) Craig A. Collard, President and Chief Executive Officer, annual base salary of \$379,600; (ii) Chenyqua Baldwin, Vice President, Finance, annual base salary of \$223,600; (iii) Brian Dickson, M.D., Chief Medical Officer, annual base salary of \$270,400; (iv) George Esgro, Vice President, Sales and Marketing, annual base salary of \$220,000; and (v) Steven M. Lutz, Executive Vice President, Commercial Operations, annual base salary of \$250,000.

In addition to his employment agreement, Mr. Collard has entered into an Executive Retention Agreement that provides for certain severance benefits in the event that his employment is terminated following a change in control of Cornerstone. The material terms of this agreement have been summarized in the section Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table beginning on page 265 of this proxy statement/prospectus.

### ***Stockholder Agreements***

In connection with the execution of the merger agreement, Mr. Collard, Ms. Baldwin, Dr. Dickson, Mr. Esgro, Mr. Lutz and Mr. McEwan entered into agreements with Critical Therapeutics that provide, among other things, that they will vote in favor of adoption of the merger agreement and grant to Critical Therapeutics an irrevocable proxy to vote all of their shares of Cornerstone common stock in favor of adoption of the merger agreement and against any proposal made in opposition to, or in competition with, the proposal to adopt the merger agreement. In addition, subject to certain exceptions, they have agreed not to transfer or otherwise dispose of any shares of common stock of the combined company or any securities convertible into or exercisable or exchangeable for shares in the combined

company for 180 days after the effective time of the merger.

**Cornerstone Stock Options and Warrants**

Each outstanding option to purchase shares of Cornerstone common stock, whether vested or unvested, and all stock option plans or other stock or equity-related plans of Cornerstone themselves, insofar as they relate to



outstanding Cornerstone's stock options, will be assumed by Critical Therapeutics and will become an option to acquire, on the same terms and conditions as were applicable under such Cornerstone stock option immediately prior to the effective time of the merger, such number of shares of Critical Therapeutics as is equal to the number of shares of Cornerstone subject to the unexercised portion of such Cornerstone stock option immediately prior to the effective time of the merger multiplied by the exchange ratio (rounded down to the nearest whole share number), at an exercise price per share equal to the exercise price per share of such Cornerstone stock option immediately prior to the effective time of the merger divided by the exchange ratio (rounded up to the nearest whole cent).

At the effective time of the merger, each warrant to purchase shares of Cornerstone common stock outstanding immediately prior to the effective time of the merger will be assumed by Critical Therapeutics and will become a warrant to acquire, on the same terms and conditions as were applicable under such Cornerstone warrant, such number of shares of Critical Therapeutics' common stock as is equal to the number of shares of Cornerstone's common stock subject to the unexercised portion of such Cornerstone warrant immediately prior to the effective time of the merger multiplied by the exchange ratio (rounded down to the nearest whole share number), at an exercise price per share equal to the exercise price per share of such Cornerstone warrant immediately prior to the effective time of the merger divided by the exchange ratio (rounded up to the nearest whole cent).

### **Form of the Merger**

Under the merger agreement, Cornerstone and the transitory subsidiary will merge, with Cornerstone surviving as a wholly owned subsidiary of Critical Therapeutics.

After completion of the merger, Critical Therapeutics will be renamed Cornerstone Therapeutics Inc. and expects to continue to trade on The NASDAQ Capital Market under the symbol CRTX.

Following the merger, the headquarters of Critical Therapeutics will be located in Cary, North Carolina, at Cornerstone's headquarters.

### **Merger Consideration**

At the effective time of the merger, all shares of Cornerstone common stock outstanding immediately prior to the effective time of the merger, including shares of Cornerstone common stock issued or issuable to Carolina Pharmaceuticals for the exchange or conversion of the outstanding principal amount of the Carolina Note, will automatically be converted into the right to receive shares of Critical Therapeutics' common stock. In addition, at the effective time of the merger, all options to purchase shares of Cornerstone common stock outstanding immediately prior to the effective time of the merger will be assumed by Critical Therapeutics and will become options to purchase shares of Critical Therapeutics' common stock and all warrants to purchase shares of Cornerstone common stock outstanding immediately prior to the effective time of the merger will be assumed by Critical Therapeutics and will become warrants to purchase shares of Critical Therapeutics' common stock. The shares of Critical Therapeutics common stock issued to Cornerstone's stockholders in connection with the merger are expected to represent approximately 70%, and Critical Therapeutics' current stockholders will own approximately 30%, of the shares of Critical Therapeutics' common stock after giving effect to shares issuable pursuant to Cornerstone's outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics' outstanding options and warrants. The exact exchange ratio per share of Cornerstone's common stock will be based in part on the number of shares of Cornerstone's common stock outstanding or issuable pursuant to outstanding options and warrants immediately prior to the effective time of the merger and will not be calculated until that time.

No certificate or scrip representing fractional shares of Critical Therapeutics' common stock will be issued in connection with the merger. Each holder of Cornerstone's common stock who would otherwise have been entitled to

receive a fraction of a share of Critical Therapeutics common stock (after taking into account all shares of Cornerstone's common stock represented by certificates delivered by such holder) shall be entitled to receive, in lieu thereof, cash (without interest) in an amount equal to such fractional part of a share of Critical Therapeutics common stock multiplied by the average last reported sales price of Critical Therapeutics

common stock at 4:00 p.m., Eastern time, end of regular trading hours on NASDAQ during the 10 consecutive trading days ending on the last trading day prior to the effective date of the merger.

The merger agreement provides that, at the effective time of the merger, Critical Therapeutics will deposit with BNY Mellon Shareowner Services or another exchange agent designated by Critical Therapeutics and reasonably acceptable to Cornerstone stock certificates representing the shares of Critical Therapeutics common stock issuable to Cornerstone's stockholders, a sufficient amount of cash to make payments in lieu of fractional shares, and any dividend or distributions to which holders of such stock certificates may be entitled.

The merger agreement provides that, as soon as reasonably practicable after the effective time of the merger, the exchange agent will mail to each record holder of Cornerstone common stock immediately prior to the effective time of the merger a letter of transmittal and instructions for surrendering and exchanging the record holder's Cornerstone stock certificates. Upon surrender of a Cornerstone common stock certificate for exchange to the exchange agent, together with a duly signed letter of transmittal, and such other documents as the exchange agent may reasonably require, the holder of the Cornerstone stock certificate will be entitled to receive the following:

a certificate representing the number of whole shares of Critical Therapeutics common stock that such holder has the right to receive pursuant to the provisions of the merger agreement;

cash in lieu of any fractional share of Critical Therapeutics common stock; and

dividends or other distributions, if any, to which they are entitled under the terms of the merger agreement.

The Cornerstone stock certificate surrendered will be cancelled.

At the effective time of the merger, all holders of certificates representing shares of Cornerstone's common stock that were outstanding immediately prior to the effective time of the merger will cease to have any rights as stockholders of Cornerstone. In addition, no transfer of Cornerstone's common stock after the effective time of the merger will be registered on the stock transfer books of Cornerstone.

If any Cornerstone stock certificate has been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming such certificate to be lost, stolen or destroyed and, if required by Critical Therapeutics, the posting by such person of a bond in such reasonable amount as Critical Therapeutics may direct as indemnity against any claim that may be made against it with respect to such certificate, the exchange agent shall issue in exchange for such lost, stolen or destroyed certificate the shares of Critical Therapeutics common stock, any cash in lieu of fractional shares, and any unpaid dividends and distributions on such shares of Critical Therapeutics common stock.

### **Effective Time of the Merger**

The merger agreement requires the parties to consummate the merger after all of the conditions to the consummation of the merger contained in the merger agreement are satisfied or waived. The merger will become effective upon the filing of a certificate of merger with the Secretary of State of the State of Delaware or at such later time as is established by Critical Therapeutics and Cornerstone and set forth in the certificate of merger. However, neither Critical Therapeutics nor Cornerstone can predict the exact timing of the consummation of the merger.

### **Regulatory Approvals**

Neither Critical Therapeutics nor Cornerstone is required to make any filings or to obtain approvals or clearances from any antitrust regulatory authorities in the United States or other countries to consummate the merger. In the United

States, Critical Therapeutics must comply with applicable federal and state securities laws and NASDAQ rules and regulations in connection with the issuance of shares of Critical Therapeutics common stock in the merger, including the filing with the SEC of this proxy statement/prospectus. As of the date hereof, the registration statement has not become effective. Prior to consummation of the merger, Critical

Therapeutics intends to file an initial listing application with The NASDAQ Capital Market pursuant to NASDAQ's reverse merger rules and to effect the listing of Critical Therapeutics' common stock issuable in connection with the merger or upon exercise of Cornerstone's outstanding stock options or warrants.

### **Material U.S. Federal Income Tax Consequences of the Merger**

The following discussion summarizes the material U.S. federal income tax consequences of the merger that are expected to apply generally to Cornerstone's stockholders upon an exchange of their Cornerstone common stock for Critical Therapeutics' common stock in the merger. This summary is based upon current provisions of the Code, existing Treasury Regulations and current administrative rulings and court decisions, all of which are subject to change and to differing interpretations, possibly with retroactive effect.

This summary only applies to a Cornerstone stockholder that is a U.S. person, defined to include:

- a citizen or resident of the United States;

- a corporation created or organized in or under the laws of the United States, or any political subdivision thereof (including the District of Columbia);

- an estate the income of which is subject to U.S. federal income taxation regardless of its source;

- a trust if either:

  - a court within the United States is able to exercise primary supervision over the administration of such trust and one or more U.S. persons have the authority to control all substantial decisions of such trust; or

  - the trust has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes; and

- any other person or entity that is treated for U.S. federal income tax purposes as if it were one of the foregoing.

Any Cornerstone stockholder other than a U.S. person as so defined is, for purposes of this discussion, a non-U.S. person. If a partnership holds Cornerstone common stock, the tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. If you are a partner of a partnership holding Cornerstone common stock, you should consult your tax advisor.

This summary assumes that Cornerstone's stockholders hold their shares of Cornerstone common stock as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment). No attempt has been made to comment on all U.S. federal income tax consequences of the merger that may be relevant to particular holders, including holders:

- who are subject to special treatment under U.S. federal income tax rules such as dealers in securities, financial institutions, non-U.S. persons, mutual funds, regulated investment companies, real estate investment trusts, insurance companies, employees of Cornerstone who will become employees of Critical Therapeutics, or tax-exempt entities;

- who are subject to the alternative minimum tax provisions of the Code;

- who acquired their shares in connection with stock option or stock purchase plans or in other compensatory transactions;

who hold their shares as qualified small business stock within the meaning of Section 1202 of the Code;

who hold their shares as part of an integrated investment such as a hedge or as part of a hedging, straddle or other risk reduction strategy; or

who do not hold their shares as capital assets.

In addition, the following discussion does not address the tax consequences of the merger under state, local and foreign tax laws or under the alternative minimum tax provisions of the Code. Furthermore, the following discussion does not address any of the:

tax consequences of transactions effectuated before, after or at the same time as the merger, whether or not they are in connection with the merger, including, without limitation, transactions in which Cornerstone shares are acquired or Critical Therapeutics shares are disposed of;

tax consequences of the receipt of Critical Therapeutics shares other than in exchange for Cornerstone shares; or

tax implications of a failure of the merger to qualify as a reorganization.

**Accordingly, holders of Cornerstone common stock are advised and expected to consult their own tax advisers regarding the U.S. federal income tax consequences of the merger to them in light of their personal circumstances and the consequences of the merger under state, local and foreign tax laws.**

As a condition to the consummation of the merger, Wilmer Cutler Pickering Hale and Dorr LLP and Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P. must render tax opinions that the merger will constitute a reorganization within the meaning of Section 368(a) of the Code, or a reorganization. The tax opinions discussed in this section are conditioned upon certain assumptions stated in the tax opinions and are based on the truth and accuracy, as of the completion of the merger, of certain representations and other statements made by Critical Therapeutics and Cornerstone in certificates delivered to counsel. If any such representations and other statements made in such certificates are inaccurate, or by the consummation of the merger becomes inaccurate, then the tax opinions may no longer be valid.

No ruling from the Internal Revenue Service, or IRS, has been or will be requested in connection with the merger. In addition, stockholders of Cornerstone should be aware that the tax opinions discussed in this section are not binding on the IRS, and the IRS could adopt a contrary position and a contrary position could be sustained by a court.

Subject to the assumptions and limitations discussed above, it is the opinion of Wilmer Cutler Pickering Hale and Dorr LLP, tax counsel to Critical Therapeutics, and Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., tax counsel to Cornerstone, that the merger will be treated for U.S. federal income tax purposes as a reorganization. Accordingly, the following material U.S. federal income tax consequences will result:

Critical Therapeutics, the transitory subsidiary and Cornerstone will not recognize any gain or loss solely as a result of the merger;

stockholders of Cornerstone will not recognize any gain or loss upon the receipt of Critical Therapeutics common stock in exchange for their Cornerstone common stock, other than with respect to cash received in lieu of fractional shares of Critical Therapeutics common stock;

the aggregate tax basis of the shares of Critical Therapeutics common stock received by a Cornerstone stockholder in the merger (including any fractional share deemed received) will be equal to the aggregate tax basis of the shares of Cornerstone common stock surrendered in exchange therefor;

the holding period of the shares of Critical Therapeutics common stock received by a Cornerstone stockholder in the merger will include the holding period of the shares of Cornerstone common stock surrendered in

exchange therefor;

generally, cash payments received by Cornerstone's stockholders in lieu of fractional shares will be treated as if such fractional shares of Critical Therapeutics' common stock were issued in the merger and then sold. A stockholder of Cornerstone who receives such cash will recognize gain or loss equal to the difference, if any, between such stockholder's basis in the fractional share and the amount of cash received; and

such gain or loss will be a capital gain or loss, and generally will constitute long-term capital gain or loss if the stockholder's holding period for the stock surrendered is more than one year as of the closing date of the merger. Net capital gain (*i.e.*, the excess of net long-term capital gain over net short-term capital loss) will be subject to tax at reduced rates for non-corporate stockholders who receive cash. The deductibility of capital losses is subject to various limitations for corporate and non-corporate holders.



For purposes of the above discussion of the bases and holding periods for shares of Cornerstone's common stock and Critical Therapeutics' common stock, stockholders who acquired different blocks of Cornerstone common stock and Critical Therapeutics' common stock at different times for different prices must calculate their gains and losses and holding periods separately for each identifiable block of such stock exchanged, converted, cancelled, or received in the merger.

The above discussion does not apply to Cornerstone's stockholders who properly perfect dissenters' rights. Generally, a Cornerstone stockholder who perfects dissenters' rights with respect to such stockholder's shares of Cornerstone common stock will recognize capital gain or loss equal to the difference between such stockholder's tax basis in such shares and the amount of cash received in exchange for such shares.

Certain noncorporate Cornerstone stockholders may be subject to backup withholding, at a rate of 28% for 2008, on cash received pursuant to the merger. Backup withholding will not apply, however, to a Cornerstone stockholder who (1) furnishes a correct taxpayer identification number and certifies that the Cornerstone stockholder is not subject to backup withholding on IRS Form W-9 or a substantially similar form, (2) provides a certification of foreign status on an appropriate Form W-8 or successor form or (3) is otherwise exempt from backup withholding. If a Cornerstone stockholder does not provide a correct taxpayer identification number on IRS Form W-9 or a substantially similar form, the Cornerstone stockholder may be subject to penalties imposed by the IRS. Amounts withheld, if any, are generally not an additional tax and may be refunded or credited against the Cornerstone stockholder's federal income tax liability, provided that the Cornerstone stockholder furnishes the required information to the IRS.

**THE PRECEDING DISCUSSION IS INTENDED ONLY AS A SUMMARY OF CERTAIN U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER AND DOES NOT PURPORT TO BE A COMPLETE ANALYSIS OR DISCUSSION OF ALL OF THE MERGER'S POTENTIAL TAX EFFECTS. CORNERSTONE STOCKHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE SPECIFIC TAX CONSEQUENCES TO THEM OF THE MERGER, INCLUDING TAX RETURN REPORTING REQUIREMENTS, AND THE APPLICABILITY AND EFFECT OF FEDERAL, STATE, LOCAL AND OTHER APPLICABLE TAX LAWS.**

### **NASDAQ Listing**

Critical Therapeutics' common stock is listed on The NASDAQ Capital Market under the symbol CRTX.

On June 13, 2008, NASDAQ approved the transfer of the listing of Critical Therapeutics' common stock from The NASDAQ Global Market to The NASDAQ Capital Market effective at the opening of business on June 17, 2008. From July 2006 to June 16, 2008, Critical Therapeutics' common stock traded on the NASDAQ Global Market. Prior to July 2006, Critical Therapeutics' common stock traded on The NASDAQ National Market, the predecessor to The NASDAQ Global Market.

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

Market's minimum stockholders' equity requirement.

Prior to consummation of the merger, Critical Therapeutics intends to file an initial listing application with The NASDAQ Capital Market pursuant to NASDAQ's reverse merger rules and to effect the listing of Critical Therapeutics' common stock issuable in connection with the merger or upon exercise of Cornerstone's outstanding stock options or warrants.

### **Anticipated Accounting Treatment**

The merger will be treated by Critical Therapeutics as a reverse merger under the purchase method of accounting in accordance with GAAP. For accounting purposes, Cornerstone is considered to be acquiring Critical Therapeutics in this transaction. Therefore, the aggregate consideration paid in connection with the merger, together with the direct costs of acquisition, will be allocated to Critical Therapeutics' tangible and intangible assets and liabilities based on their fair market values. The assets and liabilities and results of operations of Critical Therapeutics will be consolidated into the results of operations of Cornerstone as of the effective time of the merger. These allocations will be based upon a valuation that has not yet been finalized.

### **Appraisal Rights**

If the merger is completed, Cornerstone's stockholders are entitled to appraisal rights under Section 262 of the Delaware General Corporation Law, or Section 262, provided that they comply with the conditions established by Section 262.

The discussion below is not a complete summary regarding a Cornerstone stockholder's appraisal rights under Delaware law and is qualified in its entirety by reference to the text of the relevant provisions of Delaware law, which are attached to this proxy statement/prospectus as *Annex E*. Cornerstone's stockholders intending to exercise appraisal rights should carefully review *Annex E*. Failure to follow precisely any of the statutory procedures set forth in *Annex E* may result in a termination or waiver of these rights.

A record holder of shares of Cornerstone's common stock who makes the demand described below with respect to such shares, who continuously is the record holder of such shares through the effective time of the merger, who otherwise complies with the statutory requirements of Section 262 and who neither votes in favor of the merger nor consents thereto in writing will be entitled to an appraisal by the Delaware Court of Chancery, or the Delaware Court, of the fair value of his, her or its shares of Cornerstone's common stock in lieu of the consideration that such stockholder would otherwise be entitled to receive pursuant to the merger agreement. All references in this summary of appraisal rights to a stockholder or holders of shares of Cornerstone's common stock are to the record holder or holders of shares of Cornerstone's common stock. Except as set forth herein, Cornerstone's stockholders will not be entitled to appraisal rights in connection with the merger.

Under Section 262, where a merger is accomplished pursuant to Section 228 of the Delaware General Corporation Law, either a constituent corporation before the effective date of the merger, or the surviving or resulting corporation within 10 days after the effective date of the merger, must notify each stockholder of each constituent corporation entitled to appraisal rights of the approval of the merger and that appraisal rights are available to such stockholders and include in each such notice a copy of Section 262. This proxy statement/prospectus shall constitute such notice to the record holders of Cornerstone common stock.

Cornerstone's stockholders who desire to exercise their appraisal rights must satisfy all of the conditions of Section 262. Those conditions include the following:

Holders of shares of Cornerstone common stock who desire to exercise their appraisal rights must, within 20 days after the date of mailing of this notice, demand in writing the appraisal of their shares.

The written demand for appraisal must be executed by or on behalf of the stockholder of record and must reasonably inform Cornerstone of the identity of the stockholder of record and that such stockholder intends

thereby to demand appraisal of his, her or its Cornerstone common stock.

If the shares are owned of record by a person other than the beneficial owner, including a broker, fiduciary (such as a trustee, guardian or custodian), depository or other nominee, such demand must be executed by or for the record owner. If the shares are owned by or for more than one person, as in a joint tenancy or tenancy in common, such demand must be executed by or for all joint owners. An authorized agent, including an agent for two or more joint owners, may execute the demand for appraisal for a stockholder of record. However, the agent must identify the record owner and expressly disclose the fact that, in exercising the demand, he is acting as agent for the record owner. A person

having a beneficial interest in Cornerstone's common stock held of record in the name of another person, such as a broker or nominee, must act promptly to cause the record holder to follow the steps summarized herein in a timely manner to perfect whatever appraisal rights the beneficial owner may have.

A stockholder who elects to exercise appraisal rights should mail or deliver his, her or its written demand to Cornerstone at Cornerstone BioPharma Holdings, Inc., 2000 Regency Parkway, Suite 255, Cary, North Carolina 27518, Attention: Vice President, Finance.

Within ten days after the effective time of the merger, Cornerstone must provide notice of the effective time of the merger to all Cornerstone stockholders who have complied with Section 262 and have not voted in favor of the adoption of the merger agreement.

Within 120 days after the effective time of the merger, either Cornerstone or any stockholder who has complied with the required conditions of Section 262 may commence an appraisal proceeding by filing a petition in the Delaware Court, with a copy served on Cornerstone in the case of a petition filed by a stockholder, demanding a determination of the fair value of the shares of all dissenting stockholders. There is no present intent on the part of Cornerstone to file an appraisal petition, and stockholders seeking to exercise appraisal rights should not assume that Cornerstone will file such a petition or that Cornerstone will initiate any negotiations with respect to the fair value of such shares. Accordingly, holders of Cornerstone capital stock who desire to have their shares appraised should initiate any petitions necessary for the perfection of their appraisal rights within the time periods and in the manner prescribed in Section 262.

Within 120 days after the effective time of the merger, any stockholder who has satisfied the requirements of Section 262 will be entitled, upon written request, to receive from Cornerstone a statement setting forth the aggregate number of shares of Cornerstone common stock not voting in favor of the adoption of the merger agreement and with respect to which demands for appraisal were received by Cornerstone and the aggregate number of holders of such shares. A person who is the beneficial owner of shares of such stock held in a voting trust or by a nominee on behalf of such person may, in such person's own name, file a petition or request from the corporation the statement described in the previous sentence. Such statement must be mailed within 10 days after the stockholder's request has been received by Cornerstone or within 10 days after the expiration of the period for the delivery of demands as described above, whichever is later.

If a petition for an appraisal is timely filed and a copy thereof is served upon Cornerstone, Cornerstone will then be obligated, within 20 days after service, to file with the Register in Chancery a duly verified list containing the names and addresses of all stockholders who have demanded an appraisal of their shares and with whom agreements as to the value of their shares have not been reached. At the hearing on such petition, the Delaware Court will determine which stockholders are entitled to appraisal rights. The Delaware Court may require the stockholders who have demanded an appraisal for their shares and who hold stock represented by certificates to submit their certificates of stock to the Register in Chancery for notation thereon of the pendency of the appraisal proceedings; and if any stockholder fails to comply with such direction, the Delaware Court may dismiss the proceedings as to such stockholder. Where proceedings are not dismissed, the appraisal proceeding shall be conducted, as to the shares of Cornerstone capital stock owned by such stockholders, in accordance with the rules of the Delaware Court, including any rules specifically governing appraisal proceedings. Through such proceeding the Delaware Court shall determine the fair value of such shares exclusive of any element of value arising from the accomplishment or expectation of the merger, together with interest, if any, to be paid upon the amount determined to be the fair value.

Although the board of directors of Cornerstone believes that the merger consideration is fair, no representation is made as to the outcome of the appraisal of fair value as determined by the Delaware Court and stockholders should recognize that such an appraisal could result in a determination of a value higher or lower than, or the same as, the

consideration they would receive pursuant to the merger agreement. Moreover, Cornerstone does not anticipate offering more than the merger consideration to any stockholder exercising appraisal rights and reserves the right to assert, in any appraisal proceeding, that, for purposes of Section 262, the fair value of a share of Cornerstone capital stock is less than the merger consideration. In determining fair value, the Delaware Court is required to take into account all relevant factors. In *Weinberger v. UOP, Inc.*, the Delaware

Supreme Court discussed the factors that could be considered in determining fair value in an appraisal proceeding, stating that proof of value by any techniques or methods which are generally considered acceptable in the financial community and otherwise admissible in court should be considered and that [f]air price obviously requires consideration of all relevant factors involving the value of a company. The Delaware Supreme Court has stated that in making this determination of fair value the court must consider market value, asset value, dividends, earnings prospects, the nature of the enterprise and any other facts which could be ascertained as of the date of the merger which throw any light on future prospects of the merged corporation. Section 262 provides that fair value is to be exclusive of any element of value arising from the accomplishment or expectation of the merger. In *Cede & Co. v. Technicolor, Inc.*, the Delaware Supreme Court stated that such exclusion is a narrow exclusion [that] does not encompass known elements of value, but which rather applies only to the speculative elements of value arising from such accomplishment or expectation. In *Weinberger*, the Delaware Supreme Court construed Section 262 to mean that elements of future value, including the nature of the enterprise, which are known or susceptible of proof as of the date of the merger and not the product of speculation, may be considered.

The cost of the appraisal proceeding may be determined by the Delaware Court and taxed against the parties as the Delaware Court deems equitable in the circumstances. However, costs do not include attorneys' and expert witness fees. Each dissenting stockholder is responsible for his or her attorneys' and expert witness expenses, although, upon application of a dissenting stockholder, the Delaware Court may order that all or a portion of the expenses incurred by any dissenting stockholder in connection with the appraisal proceeding, including without limitation, reasonable attorneys' fees and the fees and expenses of experts, be charged pro rata against the value of all shares of stock entitled to appraisal.

Any stockholder who has duly demanded appraisal in compliance with Section 262 will not, after the effective time of the merger, be entitled to vote for any purpose any shares subject to such demand or to receive payment of dividends or other distributions on such shares, except for dividends or distributions payable to stockholders of record at a date prior to the effective time of the merger.

At any time within 60 days after the effective time of the merger, any stockholder who has not commenced an appraisal proceeding or joined that proceeding as a named party will have the right to withdraw his, her or its demand for appraisal and to accept the terms offered in the merger agreement. After this period, a stockholder may withdraw his, her or its demand for appraisal and receive payment for his, her or its shares as provided in the merger agreement only with the consent of Cornerstone. If no petition for appraisal is filed with the Delaware Court within 120 days after the effective time of the merger, stockholders' rights to appraisal will cease, and all holders of shares of Cornerstone common stock will be entitled to receive the consideration offered pursuant to the merger agreement. Inasmuch as Cornerstone has no obligation to file such a petition, and Cornerstone has no present intention to do so, any stockholder who desires a petition to be filed is advised to file it on a timely basis. Any stockholder may withdraw such stockholder's demand for appraisal by delivering to Cornerstone a written withdrawal of his, her or its demand for appraisal and acceptance of the merger consideration, except (i) that any such attempt to withdraw made more than 60 days after the effective time of the merger will require written approval of Cornerstone and (ii) that no appraisal proceeding in the Delaware Court shall be dismissed as to any stockholder without the approval of the Delaware Court, and such approval may be conditioned upon such terms as the Delaware Court deems just, provided, however, that this provision shall not affect the right of any stockholder who has not commenced an appraisal proceeding or joined that proceeding as a named party to withdraw such stockholder's demand for appraisal and to accept the terms offered upon the merger within 60 days.

Failure by any Cornerstone stockholder to comply fully with the procedures described above and set forth in *Annex E* to this proxy statement/prospectus may result in termination of such stockholder's appraisal rights.





## **THE MERGER AGREEMENT**

*The following is a summary of the material terms of the merger agreement. A copy of the merger agreement is attached as Annex A to this proxy statement/prospectus and is incorporated by reference into this proxy statement/prospectus. The merger agreement has been attached to this proxy statement/prospectus to provide you with information regarding its terms. It is not intended to provide any other factual information about Critical Therapeutics, Cornerstone or the transitory subsidiary. The following description does not purport to be complete and is qualified in its entirety by reference to the merger agreement. You should refer to the full text of the merger agreement for details of the merger and the terms and conditions of the merger agreement.*

### **General**

Under the merger agreement, Cornerstone and the transitory subsidiary, a wholly owned subsidiary of Critical Therapeutics formed in connection with the merger, will merge, with Cornerstone surviving as a wholly owned subsidiary of Critical Therapeutics. After completion of the merger, Critical Therapeutics will operate under the name Cornerstone Therapeutics Inc. Immediately following the effective time of the merger, Cornerstone's stockholders will own approximately 70%, and Critical Therapeutics' current stockholders will own approximately 30%, of Critical Therapeutics' common stock, after giving effect to shares issuable pursuant to Cornerstone's outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics' outstanding options and warrants.

The closing of the merger will occur no later than the second business day after the last of the conditions to the merger has been satisfied or waived, or at another time as Cornerstone and Critical Therapeutics agree. However, because the merger is subject to a number of conditions, neither Critical Therapeutics nor Cornerstone can predict exactly when the closing will occur or if it will occur at all.

### **Merger Consideration**

The shares of Critical Therapeutics' common stock issued or issuable to Cornerstone's stockholders in connection with the merger are expected to represent approximately 70%, and shares of Critical Therapeutics' common stock held by Critical Therapeutics' current stockholders will represent approximately 30%, of the shares of Critical Therapeutics' common stock, 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. At the effective time of the merger, each share of Cornerstone's common stock will be converted into and exchanged for the right to receive a number of shares of Critical Therapeutics' common stock equal to the product of 2.3333 multiplied by the quotient of 43,479,198, which was the number of outstanding shares of Critical Therapeutics' common stock on April 30, 2008, divided by the number of shares of Cornerstone's common stock outstanding immediately prior to the effective time of the merger, assuming the exercise or conversion of all outstanding Cornerstone options and warrants, subject to adjustment for the reverse stock split of Critical Therapeutics' common stock.

### **Amendments to Critical Therapeutics' Certificate of Incorporation**

The merger agreement provides that Critical Therapeutics' stockholders must approve, as a condition to closing the merger, an amendment to Critical Therapeutics' certificate of incorporation to effect a reverse stock split of Critical Therapeutics' common stock, which requires the affirmative vote of holders of a majority of the outstanding common stock on the record date for the special meeting. Upon the effectiveness of the amendment to Critical Therapeutics' certificate of incorporation effecting the reverse stock split, the outstanding shares of Critical Therapeutics' common

stock will be reclassified and combined into a lesser number of shares such that one share of Critical Therapeutics common stock will be issued for a specified number of shares, which shall be greater than one and equal to or less than 50, of outstanding Critical Therapeutics common stock, with the exact number within the range to be determined by Critical Therapeutics board of directors prior to the effective time of such amendment and publicly announced by Critical Therapeutics. As applicable NASDAQ initial listing standards require Critical Therapeutics to have,

among other things, a \$4.00 per share minimum bid price, the reverse stock split is necessary in order to consummate the merger.

Stockholders of record of Critical Therapeutics common stock on the record date for the special meeting will also be asked to approve an amendment to Critical Therapeutics certificate of incorporation to change the name of the corporation from Critical Therapeutics to Cornerstone Therapeutics Inc. immediately following the consummation of the merger.

### **Conditions to the Completion of the Merger**

Each party's obligation to complete the merger is subject to the satisfaction or waiver by each of the parties, at or prior to the merger, of various conditions, subject to specified exceptions, which include the following:

the stockholders of Cornerstone must adopt the merger agreement, and the stockholders of Critical Therapeutics must approve the issuance of Critical Therapeutics common stock in the merger and the amendment to Critical Therapeutics certificate of incorporation to effect the reverse stock split and change the name of Critical Therapeutics to Cornerstone Therapeutics Inc. ;

the waiting period (and any extensions thereof) applicable to the consummation of the merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and any other applicable law shall have expired or been terminated;

all authorizations, consents, orders or approvals of, or declarations or filings with, or expirations of waiting periods imposed by, any governmental entity in connection with the merger and the consummation of the other transactions contemplated by the merger agreement have been filed, been obtained or occurred;

the registration statement on Form S-4, of which this proxy statement/prospectus is a part, must have become effective under the Securities Act, no stop order suspending the effectiveness of the Form S-4 shall have been issued, and no proceeding for that purpose shall have been initiated or threatened in writing by the SEC;

there must not have been issued any order, executive order, stay, decree, judgment or injunction (preliminary or permanent) or statute, rule or regulation which is in effect and which has the effect of making the consummation of the merger illegal or otherwise prohibiting consummation of the merger or the other transactions contemplated by the merger agreement; and

there shall not be instituted or pending any action or proceeding by any governmental entity seeking to restrain, prohibit or otherwise interfere with the ownership or operation by Critical Therapeutics of Cornerstone or to compel Critical Therapeutics to dispose of or hold separate all or any portion of Cornerstone's business or assets or Critical Therapeutics business or assets, seeking to impose or confirm limitations on the ability of Critical Therapeutics effectively to exercise full rights of ownership of the shares of Cornerstone common stock or seeking to require divestiture by Critical Therapeutics of any shares of Cornerstone common stock.

In addition, each party's obligation to complete the merger is further subject to the satisfaction or waiver by that party of the following additional conditions:

all representations and warranties of the other party in the merger agreement being true and correct on the date of the merger agreement and on the closing date of the merger, as if made on the closing date of the merger or, if such representations and warranties address matters as of a specific date, then as of that specific date, except, other than with respect to representations about such party's capitalization and required approvals of the merger

agreement and related transactions, where the failure of these representations and warranties to be true and correct, disregarding any materiality qualifications, individually or in the aggregate, has not had and is not reasonably likely to have a material adverse effect on the party making the representations and warranties;

the other party to the merger agreement having performed in all material respects all obligations required to be performed by it on or before the closing of the merger;

the other party having delivered the documents required under the merger agreement for the closing of the merger, including identified third party consents and certificates from specified officers;

no material adverse effect having occurred since the date of the merger agreement and be continuing with respect to the other party; and

the receipt of a written opinion from such party's tax counsel to the effect that the merger will be treated for U.S. federal income tax purposes as a reorganization within the meaning of Section 368(a) of the Code; provided that if a party's tax counsel does not render such an opinion, this condition will nonetheless be deemed satisfied if tax counsel for the other party renders such an opinion.

In addition, the obligation of Critical Therapeutics and the transitory subsidiary to complete the merger is further subject to the satisfaction or waiver of the following conditions:

the number of shares of Cornerstone common stock held as of the effective time of the merger that have not been voted in favor of the adoption of the merger agreement and with respect to which appraisal shall have been duly demanded and perfected in accordance with Delaware law shall not exceed 5% of the number of outstanding shares of Cornerstone's common stock as of the effective time of the merger;

the exchange or conversion of the outstanding principal amount under the Carolina Note for shares of Cornerstone's common stock; and

the delivery of fully executed copies of the voting agreements of Cornerstone's stockholders and noteholders.

In addition, the obligation of Cornerstone to complete the merger is further subject to the satisfaction or waiver of the following conditions:

the delivery of fully executed copies of the stockholder agreements of Critical Therapeutics' stockholders;

NASDAQ shall have approved Critical Therapeutics' application for initial inclusion on The NASDAQ Capital Market in connection with the listing of Critical Therapeutics' common stock and the listing of shares of Critical Therapeutics issuable in connection with the merger or upon exercise of Cornerstone options and warrants; and

the availability of either ZYFLO CR or ZYFLO for purchase by third party wholesalers or retailers at all times from the date of the merger agreement through the closing of the merger, other than during any period that has not exceeded, and, as of the closing date of the merger, is not reasonably expected to exceed, 30 consecutive days.

A material adverse effect, with respect to a party, means any material adverse change, event, circumstance or development with respect to, or material adverse effect on, (i) the business, assets, liabilities, condition (financial or other), or results of operations of a party and its subsidiaries, taken as a whole, or (ii) the ability of a party and its subsidiaries to consummate the transactions contemplated by the merger agreement; provided, however, that any change or event caused by or resulting from the following shall not be deemed to be a material adverse effect (but, in the case of the first four bullets below, only to the extent that they do not have a materially disproportionate adverse

effect on the party and its subsidiaries relative to other participants in the industries or markets in which they operate):

changes in prevailing economic or market conditions in the United States or any other jurisdiction in which a party and its subsidiaries have substantial business operations;

changes or events, after the date of the merger agreement, affecting the industries in which a party and its subsidiaries operate generally;

changes, after the date of the merger agreement, in generally accepted accounting principles or requirements applicable to the party and its subsidiaries;

changes, after the date of the merger agreement, in laws, rules or regulations of general applicability or interpretations thereof by any court or governmental or regulatory authority;

the execution, delivery and performance of the merger agreement or the consummation of the transactions contemplated by the merger agreement or the announcement thereof;

any outbreak of major hostilities in which the United States is involved or any act of terrorism within the United States or directed against the facilities or citizens of the United States wherever located;

with respect to Critical Therapeutics, any issues or disruptions related to the manufacture of ZYFLO CR and its supply chain arising in connection with Critical Therapeutics' investigation of certain batches of ZYFLO CR that are on a Quality Assurance Hold or failed to meet specifications;

with respect to Critical Therapeutics, the results of Mylan's strategic alternatives process for DEY and any impact on Critical Therapeutics' co-promotion agreements with DEY; or

with respect to Critical Therapeutics, specified ordinary course operational exceptions as set forth in Critical Therapeutics' disclosure schedule to the merger agreement.

### **No Solicitation**

Each of Cornerstone and Critical Therapeutics agreed that, except as described below, neither Cornerstone nor Critical Therapeutics shall, nor shall either of them authorize or permit any of their or their respective subsidiaries' subsidiaries or any of their or their subsidiaries' respective directors, officers, employees, investment bankers, attorneys, accountants or other advisors or representatives to, directly or indirectly:

solicit, initiate, encourage or take any other action designed to facilitate any inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, any acquisition proposal, as defined below; or

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

An acquisition proposal means, with respect to any party, any inquiry, proposal or offer from any person relating to, in a single transaction or series of related transactions, any (i) acquisition of assets of such party and its subsidiaries, excluding sales of assets in the ordinary course of business consistent with past practice, equal to 10% or more of such party's consolidated assets or to which 10% or more of such party's revenues or earnings on a consolidated basis are attributable, (ii) acquisition of 10% or more of such party's outstanding common stock, (iii) tender offer or exchange offer that if consummated would result in any person beneficially owning 10% or more of such party's outstanding common stock, (iv) merger, consolidation, share exchange, business combination, recapitalization, liquidation, dissolution or similar transaction involving such party or any of its subsidiaries or (v) any combination of the foregoing types of transactions if the sum of the percentage of consolidated assets, consolidated revenues or earnings and common stock involved is 10% or more, in each case, other than the merger.

However, if at any time prior to the approval of the issuance of the shares of Critical Therapeutics common stock in the merger at the special meeting, Critical Therapeutics receives a written acquisition proposal from any person or group of persons that did not result from a breach of Critical Therapeutics obligations described above, (i) Critical Therapeutics may contact such person or group of persons to clarify the terms and conditions thereof and (ii) if Critical Therapeutics board of directors, or any committee thereof, determines in good faith, after consultation with outside legal counsel and a nationally recognized financial advisor, that such acquisition proposal constitutes or could reasonably be expected to lead to a superior proposal, as defined below, then Critical Therapeutics and its representatives may, subject to compliance with the merger agreement (x) furnish information with respect to Critical Therapeutics to the person making such acquisition



proposal and its representatives pursuant to a customary confidentiality agreement not less restrictive of the other party than the confidentiality agreement entered into between Critical Therapeutics and Cornerstone and (y) participate in discussions or negotiations with such person and its representatives regarding any superior proposal.

A superior proposal means, with respect to Critical Therapeutics, any unsolicited, bona fide written acquisition proposal on terms that Critical Therapeutics' board of directors determines in its good faith judgment to be (i) materially more favorable to the stockholders of Critical Therapeutics than the transactions contemplated by the merger agreement, taking into account all the terms and conditions of such proposal (including the likelihood and timing of consummation thereof) and the merger agreement (including any written proposal by either party to amend the terms of the merger agreement in response to such acquisition proposal or otherwise) and after consultation with outside legal counsel and a nationally recognized financial advisor, and (ii) reasonably capable of being completed on the terms proposed, taking into account all financial, regulatory, legal and other aspects of such proposal; provided, however, that no acquisition proposal shall be deemed to be a superior proposal if any financing required to consummate the acquisition proposal is not fully and irrevocably committed; and provided, further, that for purposes of the definition of superior proposal, the references to 10% in the definition of acquisition proposal shall be deemed to be references to 50% .

### **Change in Recommendation**

The merger agreement provides that neither Critical Therapeutics' board of directors nor Cornerstone's board of directors shall (i) except in the manner permitted with respect to an acquisition proposal, withdraw or modify, or publicly propose to withdraw or modify, in a manner adverse to the other party, its approval or recommendation with respect to the Critical Therapeutics proposals to issue shares of common stock in connection with the merger, effect the reverse stock split and change the name of Critical Therapeutics to Cornerstone Therapeutics Inc. or the adoption of the merger agreement by Cornerstone's stockholders, as the case may be; (ii) cause or permit such party to enter into any letter of intent, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement or similar agreement constituting or relating to any acquisition proposal, other than, with respect to Critical Therapeutics, a confidentiality agreement entered into in the circumstances permitted by the merger agreement; or (iii) adopt, approve or recommend, or propose to adopt, approve or recommend, any acquisition proposal.

Notwithstanding the foregoing, Critical Therapeutics' board of directors may withdraw or modify its recommendation with respect to its proposals to issue shares of common stock in connection with the merger, effect the reverse stock split and change the name of Critical Therapeutics to Cornerstone Therapeutics Inc. if Critical Therapeutics' board of directors determines in good faith after consultation with outside counsel that its fiduciary obligations require it to do so, but only at a time that is prior to the approval of the issuance of shares of Critical Therapeutics' common stock at the special meeting and after the fifth business day following receipt by Cornerstone of written notice advising it that Critical Therapeutics' board of directors desires to withdraw or modify the recommendation and, if such withdrawal is due to the existence of an acquisition proposal, specifying the material terms and conditions of such acquisition proposal and identifying the person making such acquisition proposal.

### **Meeting of Critical Therapeutics' Stockholders**

Critical Therapeutics is obligated under the merger agreement to call, give notice of and hold the special meeting for purposes of approving the issuance of shares of Critical Therapeutics' common stock in the merger, approving the amendment to Critical Therapeutics' certificate of incorporation to effect the reverse stock split and the amendment to Critical Therapeutics' certificate of incorporation to change the name of Critical Therapeutics to Cornerstone Therapeutics Inc.

The obligation to call, give notice of and hold the special meeting remains applicable even if Critical Therapeutics accepts or recommends a superior proposal, unless Cornerstone terminates the merger agreement.

### **Covenants; Conduct of Business Pending the Merger**

Cornerstone agreed that it will, and will cause each of its subsidiaries to, act and carry on its business in the usual, regular and ordinary course in substantially the same manner as previously conducted, pay its debts and taxes and perform its other obligations when due, comply with applicable laws, rules and regulations, and use commercially reasonable efforts, consistent with past practices, to maintain and preserve its and each of its subsidiaries' business organization, assets and properties, keep available the services of its present officers and key employees and preserve its advantageous business relationships with customers, strategic partners, suppliers, distributors and others having business dealings with it. Cornerstone also specifically agreed that, subject to specified exceptions, without the consent of Critical Therapeutics, it would not, during the period prior to the effective time of the merger:

declare, set aside or pay any dividends or make any other distributions in respect of any shares of its capital stock or repurchase any securities (other than dividends and distributions by a direct or indirect wholly owned subsidiary of Cornerstone), split, combine or reclassify its capital stock or purchase, redeem or otherwise acquire shares of its capital stock or any rights, warrants or options other than from former employees, directors and consultants;

issue, deliver, sell, grant, pledge or otherwise dispose of or encumber any securities, including options and warrants, other than the issuance of shares of Cornerstone common stock upon the exercise of options and warrants;

amend its certificate of incorporation, bylaws or other comparable charter or organizational documents;

except for purchases of inventory in the ordinary course of business consistent with past practice, acquire (i) by merging or consolidating with, or by purchasing all or a substantial portion of the assets or any stock of, or by any other manner, any business or any corporation, partnership, joint venture, limited liability company, association or other business organization or division thereof or (ii) any assets that are material, in the aggregate, to Cornerstone and its subsidiaries, taken as a whole;

except in the ordinary course of business consistent with past practice, sell, lease, license, pledge, or otherwise dispose of or encumber any properties or assets of Cornerstone or of any of its subsidiaries;

sell, dispose of or otherwise transfer any assets material to Cornerstone and its subsidiaries;

adopt or implement any stockholder rights plan;

enter into an agreement with respect to any merger, consolidation, liquidation or business combination, or any acquisition or disposition of all or substantially all of the assets or securities of Cornerstone or any of its subsidiaries;

(i) incur or permit to exist any indebtedness other than indebtedness that existed as of December 31, 2007 as reflected on Cornerstone's balance sheet or pursuant to Cornerstone's \$4.0 million line of credit with Paragon Commercial Bank in the ordinary course of business consistent with past practice or guarantee any such indebtedness of another person, (ii) issue, sell or amend any debt securities or warrants or other rights to acquire any debt securities of Cornerstone or any of its subsidiaries, guarantee any debt securities of another person, enter into any keep well or other agreement to maintain any financial statement condition of another person or enter into any arrangement having the economic effect of any of the foregoing, (iii) make any loans,

advances (other than routine advances to employees of Cornerstone in the ordinary course of business consistent with past practice) or capital contributions to, or investment in, any other person, other than Cornerstone or any of its direct or indirect wholly owned subsidiaries or (iv) enter into any hedging agreement or other financial agreement or arrangement designed to protect Cornerstone or its subsidiaries against fluctuations in commodities prices or exchange rates;

make any capital expenditures or other expenditures with respect to property, plant or equipment in excess of \$50,000 in the aggregate for Cornerstone and its subsidiaries;

make any changes in accounting methods, principles or practices, except insofar as may have been required by the SEC or a change in GAAP, or, except as so required, change any assumption underlying, or method of calculating, any bad debt, contingency or other reserve;

modify, amend or terminate any material contract or agreement to which Cornerstone or any of its subsidiaries is party, or knowingly waive, release or assign any material rights or claims, except in the ordinary course of business consistent with past practice or, to the extent subject to reserves reflected on Cornerstone's balance sheet as of December 31, 2007, in accordance with GAAP;

(i) except in the ordinary course of business consistent with past practice, enter into any material contract or agreement relating to the rendering of services or the distribution, sale or marketing by third parties of the products of, or products licensed by, Cornerstone or any of its subsidiaries or (ii) license any material intellectual property to or from any third party;

except as required to comply with applicable law or agreements, plans or arrangements existing on the date of the merger agreement, (i) take any action with respect to, adopt, enter into, terminate or amend any employment, severance or similar agreement or benefit plan for the benefit or welfare of any current or former director, officer, employee or consultant or any collective bargaining agreement, (ii) increase in any material respect the compensation or fringe benefits of, or pay any bonus to, any director, officer, employee or consultant (except for annual increases of the salaries of non-officer employees in the ordinary course), (iii) amend or accelerate the payment, right to payment or vesting of any compensation or benefits, including any outstanding Cornerstone stock options or restricted stock awards, (iv) pay any material benefit not provided for as of the date of the merger agreement under any benefit plan, (v) grant any awards under any bonus, incentive, performance or other compensation plan or arrangement or benefit plan (including the grant of stock options, stock appreciation rights, stock based or stock related awards, performance units or restricted stock, or the removal of existing restrictions in any benefit plans or agreements or awards made thereunder), except for the grant of options to purchase Cornerstone common stock to new hires, which grants shall not exceed 100,000 shares in the aggregate and 5,000 shares to any one person, and which option grants shall have an exercise price equal to the fair market value of Cornerstone common stock on the date of grant (determined in a manner consistent with Cornerstone's existing practice for establishing fair market value for option grants and which option grants shall otherwise be upon Cornerstone's customary terms) or (vi) take any action other than in the ordinary course of business consistent with past practice to fund or in any other way secure the payment of compensation or benefits under any employee plan, agreement, contract or arrangement or benefit plan;

make or rescind any material tax election, settle or compromise any material tax liability or amend any tax return except as required by applicable law;

commence any offering of shares of Cornerstone common stock pursuant to any employee stock purchase plan, permit any employee to enroll in any employee stock purchase plan or allow any participant in an employee stock purchase plan to increase the current level of such participant's payroll deductions thereunder;

initiate, compromise or settle any material litigation or arbitration proceeding;

open or close any facility or office;

fail to use commercially reasonable efforts to maintain insurance at levels substantially comparable to levels existing as of the date of the merger agreement;

fail to pay accounts payable and other obligations in the ordinary course of business consistent with past practice;

fail to use commercially reasonable efforts to maintain inventory levels in the sales channel to ensure product availability to meet expected patient demand; provided, however, that the inventory level of any individual product in the sales channel shall not exceed the aggregate sales for the preceding three

months for such product, as measured by industry standard third party data sources, such as IMS Health, National Prescription Audit or the like; or

agree or commit to take any of these restricted actions.

Critical Therapeutics agreed that it will, and will cause each of its subsidiaries to, act and carry on its business in the usual, regular and ordinary course in substantially the same manner as previously conducted, pay its debts and taxes and perform its other obligations when due, comply with applicable laws, rules and regulations, and use commercially reasonable efforts, consistent with past practices, to maintain and preserve its and each of its subsidiaries' business organization, assets and properties, keep available the services of its present officers and key employees and preserve its advantageous business relationships with customers, strategic partners, suppliers, distributors and others having business dealings with it. Critical Therapeutics also specifically agreed that, subject to limited exceptions, without the consent of Cornerstone, it would not, during the period prior to the effective time of the merger:

declare, set aside or pay any dividends or make any other distributions in respect of any shares of its capital stock or repurchase any securities (other than dividends and distributions by a direct or indirect wholly owned subsidiary of Critical Therapeutics), with the exception of the reverse stock split, split, combine or reclassify its capital stock or purchase, redeem or otherwise acquire shares of its capital stock or any rights, warrants or options other than from former employees, directors and consultants;

issue, deliver, sell, grant, pledge or otherwise dispose of or encumber any securities, including options and warrants, other than the issuance of shares of Critical Therapeutics' common stock upon exercise of options and warrants;

amend its certificate of incorporation, bylaws or other comparable charter or organizational documents, except to the extent necessary to carry into effect the reverse stock split and the change of the name of Critical Therapeutics to Cornerstone Therapeutics Inc. ;

except for purchases of inventory in the ordinary course of business consistent with past practice, acquire (i) by merging or consolidating with, or by purchasing all or a substantial portion of the assets or any stock of, or by any other manner, any business or any corporation, partnership, joint venture, limited liability company, association or other business organization or division thereof or (ii) any assets that are material, in the aggregate, to Critical Therapeutics and its subsidiaries, taken as a whole;

except in the ordinary course of business consistent with past practice, sell, lease, license, pledge, or otherwise dispose of or encumber any properties or assets;

sell, dispose of or otherwise transfer any assets material to Critical Therapeutics;

adopt or implement any stockholder rights plan;

except for a confidentiality agreement as permitted in connection with an acquisition proposal, enter into an agreement with respect to any merger, consolidation, liquidation or business combination, or any acquisition or disposition of all or substantially all of the assets or securities of Critical Therapeutics;

(i) incur or permit to exist any indebtedness for borrowed money or guarantee any such indebtedness of another person, (ii) issue, sell or amend any debt securities or warrants or other rights to acquire any debt securities of Critical Therapeutics, guarantee any debt securities of another person, enter into any keep well or other agreement to maintain any financial statement condition of another person or enter into any arrangement

having the economic effect of any of the foregoing, (iii) make any loans, advances (other than routine advances to employees of Critical Therapeutics in the ordinary course of business consistent with past practice) or capital contributions to, or investment in, any other person, other than Critical Therapeutics or any of its direct or indirect wholly owned subsidiaries or (iv) enter into any hedging agreement or other financial agreement or arrangement designed to protect Critical Therapeutics or its subsidiaries against fluctuations in commodities prices or exchange rates;



make any capital expenditures or other expenditures with respect to property, plant or equipment in excess of \$50,000 in the aggregate for Critical Therapeutics and its subsidiaries, taken as a whole, other than as set forth in Critical Therapeutics' budget for capital expenditures made available to Cornerstone or specific capital expenditures disclosed and set forth on Critical Therapeutics' disclosure schedule;

make any changes in accounting methods, principles or practices, except insofar as may have been required by the SEC or a change in GAAP or, except as so required, change any assumption underlying, or method of calculating, any bad debt, contingency or other reserve;

modify, amend or terminate any material contract or agreement to which Critical Therapeutics is party, or knowingly waive, release or assign any material rights or claims (including any write-off or other compromise of any accounts receivable of Critical Therapeutics or any of its subsidiaries), except in the ordinary course of business consistent with past practice or, to the extent subject to reserves reflected on the Critical Therapeutics balance sheet as of December 31, 2007, in accordance with GAAP;

(i) except in the ordinary course of business consistent with past practice, enter into any material contract or agreement relating to the rendering of services or the distribution, sale or marketing by third parties of the products of, or products licensed by, Critical Therapeutics or (ii) license any material intellectual property to or from any third party;

except as required to comply with applicable law or agreements, plans or arrangements existing on the date of the merger agreement, (i) take any action with respect to, adopt, enter into, terminate or amend any employment, severance or similar agreement or benefit plan for the benefit or welfare of any current or former director, officer, employee or consultant or any collective bargaining agreement, (ii) increase in any material respect the compensation or fringe benefits of, or pay any bonus to, any director, officer, employee or consultant (except for annual increases of the salaries of non-officer employees in the ordinary course), (iii) amend or accelerate the payment, right to payment or vesting of any compensation or benefits, including any outstanding Critical Therapeutics stock option or restricted stock awards, (iv) pay any material benefit not provided for as of the date of the merger agreement under any benefit plan, (v) grant any awards under any bonus, incentive, performance or other compensation plan or arrangement or benefit plan (including the grant of stock options, stock appreciation rights, stock based or stock related awards, performance units or restricted stock, or the removal of existing restrictions in any benefit plans or agreements or awards made thereunder), except for the grant of options to purchase Critical Therapeutics' common stock to new hires, which grants shall not exceed 100,000 shares in the aggregate and 5,000 shares to any one person, and which option grants shall have an exercise price equal to the fair market value of Critical Therapeutics' common stock on the date of grant (determined in a manner consistent with Critical Therapeutics' existing practice for establishing fair market value for option grants and which option grants shall otherwise be upon Critical Therapeutics' customary terms) or (vi) take any action other than in the ordinary course of business consistent with past practice to fund or in any other way secure the payment of compensation or benefits under any employee plan, agreement, contract or arrangement or benefit plan;

make or rescind any material tax election, settle or compromise any material tax liability or amend any tax return except as required by applicable law;

commence any offering of shares of Critical Therapeutics' common stock pursuant to any employee stock purchase plan, permit any employee to enroll in any employee stock purchase plan or allow any participant in an employee stock purchase plan to increase the current level of such participant's payroll deductions thereunder;

initiate, compromise or settle any material litigation or arbitration proceeding;

open or close any facility or office;

fail to use commercially reasonable efforts to maintain insurance at levels substantially comparable to levels existing as of the date of the merger agreement;

fail to pay accounts payable and other obligations in the ordinary course of business consistent with past practice;

fail to use commercially reasonable efforts to maintain inventory levels in the sales channel to ensure product availability to meet expected patient demand; provided, however, that the inventory level of any individual product in the sales channel shall not exceed the aggregate sales for the preceding three months for such product, as measured by industry standard third party data sources, such as IMS Health, National Prescription Audit or the like;

fail to appropriately adjust any Critical Therapeutics stock options or warrants so that the exercise prices and number of shares issuable upon exercise provide the holder the same economic benefit as existed immediately prior to the reverse stock split; or

agree or commit to take any of these restricted actions.

### **Other Agreements**

Each of Cornerstone and Critical Therapeutics has agreed to use its commercially reasonable efforts to:

take all actions necessary to complete the merger;

promptly file or otherwise submit all applications, notices, reports and other documents reasonably required to be filed with a governmental entity with respect to the merger;

obtain any approvals under applicable antitrust laws and lift any injunction prohibiting the merger or other transactions contemplated by the merger agreement under antitrust laws;

obtain all consents, approvals or waivers reasonably required in connection with the transactions contemplated by the merger agreement;

consult and agree with each other about any public statement or press release either will make concerning the merger; and

cause the merger to qualify as a reorganization within the meaning of Section 368(a) of the Code.

Cornerstone and Critical Therapeutics also have agreed:

that Critical Therapeutics will, in consultation with Cornerstone, file an application for initial inclusion on The NASDAQ Capital Market in connection with the listing of Critical Therapeutics common stock in connection with NASDAQ's reverse merger rules and to effect the listing of Critical Therapeutics common stock issuable in connection with the merger or upon exercise of Cornerstone's outstanding stock options or warrants;

to provide reasonable access to information to the other party and to coordinate with the other in preparing and exchanging information and to promptly provide the other with copies of all filings or submissions made in connection with the merger;

that for a period of six years after the merger, the combined company will indemnify each of the directors and officers of Critical Therapeutics to the fullest extent permitted by law and will maintain directors and officers

liability insurance for Critical Therapeutics directors and officers;

to use reasonable efforts to consult and agree with each other about any statement or materials sent to employees; and

to notify the other party of any event, the occurrence of which would be reasonably likely to cause a representation or warranty in the merger agreement to be inaccurate or untrue or any material failure of a party to comply with or satisfy a covenant or condition in the merger agreement.

## Termination

The merger agreement may be terminated at any time before the completion of the merger, whether before or after the required Cornerstone stockholder approval of the merger has been obtained, as set forth below:

by mutual written consent of Cornerstone and Critical Therapeutics;

by either Cornerstone or Critical Therapeutics if the merger has not been completed by November 30, 2008, but this right to terminate the merger agreement will not be available to any party whose failure to fulfill any obligation under the merger agreement has been a principal cause of or resulted in the failure of the merger to be completed by such date;

by either Cornerstone or Critical Therapeutics if a governmental entity has issued a nonappealable final order, decree or ruling or taken any other nonappealable final action that permanently restrains, enjoins or otherwise prohibits the merger;

by either Cornerstone or Critical Therapeutics if Critical Therapeutics' stockholders do not approve each of the proposals presented at the special meeting at which a vote on such proposals is taken, but this right to terminate the merger agreement will not be available (i) to a party if such party is in breach of or has failed to fulfill its obligations under the merger agreement or (ii) to Critical Therapeutics if the failure to obtain the requisite vote was caused by a breach by any party other than Cornerstone of the stockholder agreements entered into with Critical Therapeutics' stockholders in connection with the merger;

by Critical Therapeutics if (i) Cornerstone's board of directors fails to recommend that Cornerstone's stockholders vote to approve the merger agreement and the merger or withdraws or modifies its recommendation, (ii) after the receipt by Cornerstone of an acquisition proposal, Cornerstone's board of directors fails to reconfirm its recommendation of the merger agreement or the merger within five business days after a request by Critical Therapeutics for such reconfirmation, (iii) Cornerstone's board of directors approves or recommends to Cornerstone's stockholders any acquisition proposal, (iv) a tender offer or exchange offer for outstanding shares of Cornerstone's common stock is commenced and Cornerstone's board of directors recommends that Cornerstone's stockholders tender their shares in such offer or fails to recommend against acceptance of such offer within 10 business days following commencement of such offer or (v) Cornerstone breaches its non-solicitation obligations or stockholder covenants (each of clauses (i) through (v) above is referred to herein as a "Cornerstone Triggering Event");

by Cornerstone if (i) Critical Therapeutics' board of directors fails to recommend that Critical Therapeutics stockholders vote for the proposals presented at the special meeting or withdraws or modifies its recommendation, (ii) after the receipt by Critical Therapeutics of an acquisition proposal, Critical Therapeutics board of directors fails to reconfirm its recommendation of the merger agreement or the merger within five business days after a request by Cornerstone for such reconfirmation, (iii) Critical Therapeutics' board of directors approves or recommends to Critical Therapeutics' stockholders any acquisition proposal, (iv) a tender offer or exchange offer for outstanding shares of Critical Therapeutics' common stock is commenced (other than by Cornerstone or its affiliates) and Critical Therapeutics' board of directors recommends that Critical Therapeutics' stockholders tender their shares in such offer or fails to recommend against acceptance of such offer within 10 business days following commencement of such offer, (v) Critical Therapeutics breaches its non-solicitation obligations or (vi) Critical Therapeutics fails to hold the special meeting of its stockholders by one business day prior to November 30, 2008 (each of clauses (i) through (vi) above is referred to herein as a

Critical Therapeutics Triggering Event );

by either Cornerstone or Critical Therapeutics if there has been a breach of or failure to perform any representation, warranty, covenant or agreement set forth in the merger agreement by the other party which breach would cause conditions to the closing of the merger not to be satisfied, and such failure or breach with respect to any such representation, warranty, covenant or agreement cannot be cured or, if curable, shall continue unremedied for a period of 30 days after receipt of written notice from the

non-breaching party of the occurrence of such failure or breach, provided that in no event shall such 30 day period extend beyond the second business day immediately preceding November 30, 2008, which written notice must be provided promptly following such time as such party obtains actual knowledge of such failure or breach (the events above are referred to herein as an *Uncured Breach* );

by Critical Therapeutics if Cornerstone does not obtain stockholder approval of the merger agreement by delivery of the written consents of Cornerstone's stockholders by 5:00 p.m., New York City time, on May 2, 2008; or

by Critical Therapeutics if (i) Cornerstone has not engaged a new independent registered public accounting firm by May 22, 2008, (ii) the audit of Cornerstone's financial statements as of the end of and for each of the last three fiscal years and a review in accordance with Statement on Auditing Standards No. 100 of the unaudited financial statements required to be included in this Form S-4 by Cornerstone's new auditors has not been completed by August 31, 2008 or (iii) the audit performed by Cornerstone's new auditors reflects a material adverse change with respect to the assets, liabilities, capitalization, financial condition or results of operations of Cornerstone as compared to the financial statements delivered by Cornerstone for such periods prior to the execution of the merger agreement (each of clauses (i) through (iii) above is referred to herein as the *Cornerstone Audit Requirements* ).

## **Termination Fee**

### ***Fee Payable by Critical Therapeutics***

Critical Therapeutics must pay Cornerstone a termination fee of \$1.0 million if the merger agreement is terminated (i) by Cornerstone because the merger has not occurred by November 30, 2008 if the merger has not occurred by such date due to the failure of Critical Therapeutics to satisfy closing conditions relating to approval by Critical Therapeutics' stockholders of the proposals presented at the special meeting, the fulfillment of Critical Therapeutics' obligations under the merger agreement or delivery of the stockholder agreements entered into with Critical Therapeutics' stockholders, (ii) by Cornerstone or Critical Therapeutics because Critical Therapeutics' stockholders failed to approve the proposals presented at the special meeting if at or prior to the time of such failure an acquisition proposal relating to Critical Therapeutics was announced and was not abandoned or withdrawn or (iii) by Cornerstone because of the occurrence of a Critical Therapeutics Triggering Event or an Uncured Breach by Critical Therapeutics.

In addition, Critical Therapeutics must pay Cornerstone up to \$150,000 as reimbursement for expenses incurred in connection with the merger if the merger agreement is terminated (i) by either Cornerstone or Critical Therapeutics because the merger has not occurred by November 30, 2008 if the merger has not occurred by such date due to the failure of Critical Therapeutics to satisfy closing conditions relating to approval by Critical Therapeutics' stockholders of the proposals presented at the special meeting, the accuracy of Critical Therapeutics' representations and warranties, the fulfillment of Critical Therapeutics' obligations under the merger agreement or delivery of the stockholder agreements of Critical Therapeutics' stockholders, (ii) by either Cornerstone or Critical Therapeutics because Critical Therapeutics' stockholders failed to approve the proposals presented at the special meeting or (iii) by Cornerstone because of the occurrence of a Critical Therapeutics Triggering Event or an Uncured Breach by Critical Therapeutics.

### ***Fee Payable by Cornerstone***

Cornerstone must pay Critical Therapeutics a termination fee of \$1.0 million if the merger agreement is terminated by Critical Therapeutics because (i) the merger has not occurred by November 30, 2008 if the merger has not occurred by such date due to the failure of Cornerstone to satisfy closing conditions relating to approval of the merger agreement and the merger by Cornerstone's stockholders, the fulfillment of Cornerstone's obligations under the merger agreement,

the conversion or exchange of the outstanding principal amount of the Carolina Note into shares of Cornerstone's common stock, delivery of the noteholder agreement entered into with Carolina Pharmaceuticals or delivery of the stockholder agreements entered into with Cornerstone's stockholders, (ii) a Cornerstone Triggering Event or an Uncured Breach by Cornerstone has occurred, (iii) Cornerstone has not obtained stockholder approval of the written consents of Cornerstone's



stockholders by 5:00 p.m., New York City time, on May 2, 2008, (iv) Cornerstone's failure to meet the Cornerstone Audit Requirements or (v) the audit performed by Cornerstone's new auditor reflects a material adverse change as compared to the financial statements delivered by Cornerstone for such periods prior to the execution of the merger agreement.

In addition, Cornerstone must pay Critical Therapeutics up to \$100,000 as reimbursement for expenses incurred in connection with the merger if the merger agreement is terminated (i) by either Cornerstone or Critical Therapeutics because the merger has not occurred by November 30, 2008 if the merger has not occurred by such date due to the failure of Cornerstone to satisfy closing conditions relating to approval of the merger agreement and the merger by Cornerstone's stockholders, the accuracy of Cornerstone's representations and warranties, the fulfillment of Cornerstone's obligations under the merger agreement, the conversion or exchange of the outstanding principal amount of the Carolina Note into shares of Cornerstone's common stock, delivery of the noteholder agreement entered into with Carolina Pharmaceuticals or delivery of the stockholder agreements of Cornerstone's stockholders or (ii) by Critical Therapeutics due to (A) a Cornerstone Triggering Event, (B) an Uncured Breach by Cornerstone, (C) Cornerstone's failure to obtain approval by its stockholders of the merger agreement and merger or (D) Cornerstone's failure to meet the Cornerstone Audit Requirements.

### **Representations and Warranties**

The merger agreement contains customary representations and warranties of Critical Therapeutics, Cornerstone and the transitory subsidiary for a transaction of this type. Critical Therapeutics' representations and warranties are qualified by its disclosure schedules and, in some cases, by Critical Therapeutics' SEC reports. Cornerstone's representations and warranties are qualified by its disclosure schedules. The representations and warranties in the merger agreement relate to, among other things:

corporate organization, standing and power;

capital structure;

subsidiaries;

authority, no conflict, required filings and consents;

financial statements and, with respect to Critical Therapeutics, documents filed with the SEC and the accuracy of information contained in those documents;

any undisclosed liabilities;

any material changes or events;

tax matters;

owned and leased real property;

intellectual property;

agreements, contracts and commitments;

litigation matters;

environmental matters;

employment benefit plans;

employee and labor matters;

compliance with laws

permits and regulatory matters;

agreements with employees;

insurance matters;

with respect to Critical Therapeutics, the opinion of Critical Therapeutics' financial advisor;

with respect to Critical Therapeutics, the inapplicability of the provisions of Section 203 of the Delaware General Corporation Law to the merger;

the absence of any existing discussions regarding an acquisition proposal;

controls and procedures, certifications and other matters related to the Sarbanes-Oxley Act;

with respect to Cornerstone, transactions with affiliates;

brokers' fees and expenses;

with respect to Cornerstone, books and records; and

with respect to Critical Therapeutics, the operations of the transitory subsidiary.

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the merger, but their accuracy forms the basis of one of the conditions to the obligations of Cornerstone and Critical Therapeutics to complete the merger.

#### **Amendment**

The merger agreement may be amended by the parties by action taken or authorized by their respective board of directors, at any time before or after approval of the matters presented in connection with the merger by the stockholders of any of the parties, but, after any such approval, no amendment shall be made which by law requires further approval of such stockholders without such further approval.

#### **Cornerstone Operating Company Guarantee**

Cornerstone BioPharma, Inc., a Nevada corporation and a wholly owned subsidiary of Cornerstone, is guaranteeing the performance by Cornerstone of its obligations under the merger agreement and is jointly and severally liable for payment of any termination fee or expenses owing to Critical Therapeutics under the merger agreement.

## **AGREEMENTS RELATED TO THE MERGER**

### **Cornerstone Stockholder Agreements**

In connection with the execution of the merger agreement, holders of a majority of the shares of Cornerstone's outstanding common stock have entered into agreements with Critical Therapeutics that provide, among other things, that the stockholders will vote in favor of adoption of the merger agreement and grant to Critical Therapeutics an irrevocable proxy to vote all of such stockholders' shares of Cornerstone common stock in favor of adoption of the merger agreement and against any proposal made in opposition to, or in competition with, the proposal to adopt the merger agreement. In addition, these Cornerstone stockholders have agreed not to transfer or otherwise dispose of any shares of Critical Therapeutics' common stock that they receive in the merger for 180 days after the effective time of the merger. In addition, certain directors and officers of Cornerstone that hold options to acquire Cornerstone's common stock have entered into identical stockholder agreements that would apply to any Cornerstone stock beneficially owned at the effective time of the merger.

The Cornerstone stockholders and option holders that entered into the stockholder agreements with Critical Therapeutics are Cornerstone BioPharma Holdings, Ltd., Craig A. Collard, Craig Collard Irrevocable Trust, James V. Baker, Chenyqua Baldwin, Lutz Family Limited Partnership, Alastair McEwan, George Esgro, Brian Dickson, and Steven M. Lutz.

### **Cornerstone Noteholder Agreement**

Carolina Pharmaceuticals, which is the holder of the Carolina Note, has entered into an agreement that provides, among other things, for the conversion or exchange of the outstanding principal amount of the Carolina Note into shares of Cornerstone's common stock prior to the effective time of the merger and for the same voting and lock-up provisions provided for pursuant to the agreements that Cornerstone's other stockholders have entered into.

### **Critical Therapeutics Stockholder Agreements**

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

The Critical Therapeutics stockholders that entered into the voting agreements with Cornerstone are HealthCare Ventures VI, L.P., HealthCare Ventures VII, L.P., Advanced Technology Ventures VII, L.P., Advanced Technology Ventures VII (B), L.P., Advanced Technology Ventures VII (C), L.P., ATV Entrepreneurs VII, L.P., ATV Alliance 2003, L.P., Advanced Technology Ventures VI, L.P. and ATV Entrepreneurs VI, L.P.

## **MATTERS BEING SUBMITTED TO A VOTE OF CRITICAL THERAPEUTICS STOCKHOLDERS**

### **Proposal 1: Approval of the Issuance of Common Stock in the Merger**

#### ***General***

At the special meeting, Critical Therapeutics stockholders will be asked to approve the issuance of Critical Therapeutics common stock pursuant to the merger agreement. Immediately following the effective time of the merger, Cornerstone's stockholders will own approximately 70%, and Critical Therapeutics current stockholders will own approximately 30%, of Critical Therapeutics common stock, after giving effect to shares issuable pursuant to Cornerstone's outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics outstanding options and warrants, subject to various assumptions and conditions described in detail in this proxy statement/prospectus. The terms of, reasons for and other aspects of the merger agreement and the issuance of Critical Therapeutics common stock pursuant to the merger agreement are described in detail in the other sections of this proxy statement/prospectus.

The full text of the merger agreement is attached to this proxy statement/prospectus as *Annex A*.

#### ***Required Vote; Recommendation of Board of Directors***

The affirmative vote of the holders of a majority of the shares of Critical Therapeutics common stock present in person or represented by proxy and voting on such matter at the special meeting is required for approval of Proposal 1.

A failure to submit a proxy card or vote at the special meeting, or an abstention, vote withheld or broker non-vote will have no effect on the outcome of Proposal 1.

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 1 TO APPROVE THE ISSUANCE OF CRITICAL THERAPEUTICS COMMON STOCK PURSUANT TO THE MERGER AGREEMENT.**

### **Proposal 2: Approval of the Reverse Stock Split**

#### ***General***

At the special meeting, Critical Therapeutics stockholders will be asked to approve an amendment to Critical Therapeutics certificate of incorporation to effect a reverse stock split of the issued and outstanding shares of Critical Therapeutics common stock. Upon the effectiveness of the amendment to Critical Therapeutics certificate of incorporation effecting the reverse stock split, the outstanding shares of Critical Therapeutics common stock will be reclassified and combined into a lesser number of shares such that one share of Critical Therapeutics common stock will be issued for a specified number of shares, which shall be greater than one and equal to or less than 50, of outstanding Critical Therapeutics common stock, with the exact number within the range to be determined by Critical Therapeutics board of directors prior to the effective time of such amendment and publicly announced by Critical Therapeutics. If Proposal 2 is approved, the reverse stock split would become effective immediately prior to the effective time the merger. Critical Therapeutics board of directors may effect only one reverse stock split in connection with this Proposal 2. Critical Therapeutics board of directors decision will be based on a number of factors, including market conditions, existing and expected trading prices for Critical Therapeutics common stock and

the listing requirements of The NASDAQ Capital Market. Even if the stockholders approve the reverse stock split, Critical Therapeutics reserves the right not to effect the reverse stock split if Critical Therapeutics board of directors does not deem the reverse stock split to be in the best interests of Critical Therapeutics and its stockholders. Critical Therapeutics board of directors may determine to effect the reverse stock split, if it is approved by the stockholders, even if the other proposals to be acted upon at the meeting are not approved, including the issuance of shares of Critical Therapeutics common stock in the merger.

The form of the proposed amendment to the Critical Therapeutics certificate of incorporation to effect the reverse stock split, as more fully described below, will effect the reverse stock split but will not change the number of authorized shares, or the par value, of Critical Therapeutics common stock.

***Purpose***

Critical Therapeutics board of directors approved the proposal authorizing the reverse stock split for the following reasons:

because the initial listing standards of The NASDAQ Capital Market will require Critical Therapeutics to have, among other things, a \$4.00 per share minimum bid price upon the closing of the merger, the reverse stock split is necessary in order to consummate the merger;

the board of directors believes effecting the reverse stock split may be an effective means of avoiding a delisting of Critical Therapeutics common stock from The NASDAQ Capital Market in the future; and

the board of directors believes a higher stock price may help generate investor interest in Critical Therapeutics and help Critical Therapeutics attract and retain employees.

If the reverse stock split successfully increases the per share price of Critical Therapeutics common stock, Critical Therapeutics board of directors believes that this may increase trading volume in Critical Therapeutics common stock and facilitate future financings by Critical Therapeutics.

***NASDAQ Requirements for Listing on The NASDAQ Capital Market***

Critical Therapeutics common stock is listed on The NASDAQ Capital Market under the symbol CRTX.

According to NASDAQ rules, an issuer must, in a case such as this, apply for initial inclusion following a transaction whereby the issuer combines with a non-NASDAQ entity, resulting in a change of control of the issuer and potentially allowing the non-NASDAQ entity to obtain a NASDAQ listing. These are referred to as NASDAQ's reverse merger rules. Accordingly, the listing standards of The NASDAQ Capital Market will require Critical Therapeutics to have, among other things, a \$4.00 per share minimum bid price upon the effective time of the merger. Therefore, the reverse stock split is necessary in order to consummate the merger.

Additionally, Critical Therapeutics board of directors believes that maintaining its listing on The NASDAQ Capital Market may provide a broader market for Critical Therapeutics common stock and facilitate the use of Critical Therapeutics common stock in financing and other transactions. Critical Therapeutics board of directors unanimously approved the reverse stock split partly as a means of maintaining the share price of Critical Therapeutics common stock following the merger above \$4.00 per share.

One of the effects of the reverse stock split will be to effectively increase the proportion of authorized shares which are unissued relative to those which are issued. This could result in the combined company being able to issue more shares without further stockholder approval. Critical Therapeutics currently has no plans to issue shares, other than in connection with the merger, and to satisfy obligations under Critical Therapeutics employee stock options and warrants from time to time as these options and warrants are exercised. The reverse stock split will not affect the number of authorized shares of Critical Therapeutics common stock, which will continue to be 90,000,000.

***Potential Increased Investor Interest***

On June 30, 2008, Critical Therapeutics common stock closed at \$0.37 per share. In approving the proposal authorizing the reverse stock split, Critical Therapeutics board of directors considered that Critical Therapeutics common stock may not appeal to brokerage firms that are reluctant to recommend lower priced securities to their clients. Investors may also be dissuaded from purchasing lower priced stocks because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Moreover, the analysts at many brokerage firms do not monitor the trading activity or otherwise provide coverage of lower priced stocks. Also, Critical Therapeutics board of directors believes that most investment funds are reluctant to invest in lower priced stocks.



There are risks associated with the reverse stock split, including that the reverse stock split may not result in an increase in the per share price of Critical Therapeutics common stock.

Critical Therapeutics cannot predict whether the reverse stock split will increase the market price for Critical Therapeutics common stock. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

the market price per share of Critical Therapeutics common stock after the reverse stock split will rise in proportion to the reduction in the number of shares of Critical Therapeutics common stock outstanding before the reverse stock split;

the reverse stock split will result in a per share price that will attract brokers and investors who do not trade in lower priced stocks;

the reverse stock split will result in a per share price that will increase Critical Therapeutics ability to attract and retain employees; or

the market price per share will either exceed or remain in excess of the \$1.00 minimum bid price as required by NASDAQ for continued listing, or that Critical Therapeutics will otherwise meet the requirements of NASDAQ for inclusion for trading on The NASDAQ Capital Market.

The market price of Critical Therapeutics common stock will also be based on Critical Therapeutics performance and other factors, some of which are unrelated to the number of shares outstanding. If the reverse stock split is effected and the market price of Critical Therapeutics common stock declines, the percentage decline as an absolute number and as a percentage of Critical Therapeutics overall market capitalization may be greater than would occur in the absence of a reverse stock split. Furthermore, the liquidity of Critical Therapeutics common stock could be adversely affected by the reduced number of shares that would be outstanding after the reverse stock split.

### ***Principal Effects of the Reverse Stock Split***

If the stockholders approve the proposal to implement the reverse stock split and Critical Therapeutics board of directors implements the reverse stock split, Critical Therapeutics will amend Critical Therapeutics certificate of incorporation to effect the reverse stock split. The text of the form of the proposed amendment to Critical Therapeutics certificate of incorporation is attached to this proxy statement/prospectus as *Annex B*.

The reverse stock split will be effected simultaneously for all outstanding shares of Critical Therapeutics common stock. The reverse stock split will affect all of Critical Therapeutics stockholders uniformly and will not affect any stockholder's percentage ownership interests in Critical Therapeutics, except to the extent that the reverse stock split results in any of Critical Therapeutics stockholders owning a fractional share. Common stock issued pursuant to the reverse stock split will remain fully paid and nonassessable. The reverse stock split will not affect Critical Therapeutics continuing to be subject to the periodic reporting requirements of the Exchange Act.

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

***Procedure for Effecting Reverse Stock Split and Exchange of Stock Certificates***

If Critical Therapeutics stockholders approve the proposal to effect the reverse stock split, and if Critical Therapeutics board of directors still believes that a reverse stock split is in the best interests of Critical Therapeutics and its stockholders, Critical Therapeutics board of directors will determine the ratio of the reverse stock split to be implemented. Critical Therapeutics will file the certificate of amendment with the

Secretary of State of the State of Delaware immediately prior to the effective time of the merger. Critical Therapeutics board of directors may delay effecting the reverse stock split without resoliciting stockholder approval. Beginning on the effective date of the reverse stock split, each certificate representing pre-split shares will be deemed for all corporate purposes to evidence ownership of post-split shares.

As soon as practicable after the effective date of the reverse stock split, stockholders will be notified that the reverse stock split has been effected. Critical Therapeutics expects that Critical Therapeutics transfer agent will act as exchange agent for purposes of implementing the exchange of stock certificates. Holders of pre-split shares will be asked to surrender to the exchange agent certificates representing pre-split shares in exchange for certificates representing post-split shares in accordance with the procedures to be set forth in a letter of transmittal to be sent by Critical Therapeutics. No new certificates will be issued to a stockholder until such stockholder has surrendered such stockholder's outstanding certificate(s) together with the properly completed and executed letter of transmittal to the exchange agent. Any pre-split shares submitted for transfer, whether pursuant to a sale or other disposition, or otherwise, will automatically be exchanged for post-split shares. **STOCKHOLDERS SHOULD NOT DESTROY ANY STOCK CERTIFICATE(S) AND SHOULD NOT SUBMIT ANY CERTIFICATE(S) UNLESS AND UNTIL REQUESTED TO DO SO.**

### ***Fractional Shares***

No certificates or scrip representing fractional shares of Critical Therapeutics common stock will be issued in connection with the reverse stock split. Each holder of Critical Therapeutics common stock who would otherwise have been entitled to receive a fraction of a share of Critical Therapeutics common stock (after taking into account all fractional shares of Critical Therapeutics common stock otherwise issuable to such holder) shall be entitled to receive, in lieu thereof, upon surrender of such holder's certificate(s) representing such fractional shares of Critical Therapeutics common stock, cash (without interest) in an amount equal to such fractional part of a share of Critical Therapeutics common stock multiplied by the average last reported sales price of Critical Therapeutics common stock at 4:00 p.m., Eastern time, end of regular trading hours on NASDAQ during the 10 consecutive trading days ending on the last trading day prior to the effective date of the merger.

By authorizing the reverse stock split, stockholders will be approving the combination of any whole number of shares of common stock between and including a number that is greater than one and less than or equal to 50 into one share. The certificate of amendment filed with the Secretary of State of the State of Delaware will include only that number determined by the board of directors to be in the best interests of Critical Therapeutics and its stockholders. In accordance with these resolutions, the board of directors will not implement any amendment providing for a different split ratio.

Critical Therapeutics stockholders should be aware that, under the escheat laws of the various jurisdictions where stockholders reside, where Critical Therapeutics is domiciled, and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective date of the split may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by Critical Therapeutics or the exchange agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, stockholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

### ***Accounting Matters***

The reverse stock split will not affect the common stock capital account on Critical Therapeutics balance sheet. However, because the par value of Critical Therapeutics common stock will remain unchanged on the effective date of the split, the components that make up the common stock capital account will change by offsetting amounts.

Depending on the size of the reverse stock split the board of directors decides to implement, the stated capital component will be reduced and the additional paid-in capital component will be increased with the amount by which the stated capital is reduced. The per share net income or loss and net book value of Critical Therapeutics will be increased because there will be fewer shares of Critical

Therapeutics common stock outstanding. Prior periods per share amounts will be restated to reflect the reverse stock split.

***Potential Anti-Takeover Effect***

Although the increased proportion of unissued authorized shares to issued shares could, under certain circumstances, have an anti-takeover effect, for example, by permitting issuances that would dilute the stock ownership of a person seeking to effect a change in the composition of Critical Therapeutics board of directors or contemplating a tender offer or other transaction for the combination of Critical Therapeutics with another company, the reverse stock split proposal is not being proposed in response to any effort of which Critical Therapeutics is aware to accumulate shares of Critical Therapeutics common stock or obtain control of Critical Therapeutics, other than in connection with the merger with Cornerstone, nor is it part of a plan by management to recommend a series of similar amendments to Critical Therapeutics board of directors and stockholders. Other than the proposals being submitted to Critical Therapeutics stockholders for their consideration at the special meeting, Critical Therapeutics board of directors does not currently contemplate recommending the adoption of any other actions that could be construed to affect the ability of third parties to take over or change control of Critical Therapeutics.

***No Appraisal Rights***

Under the Delaware General Corporation Law, Critical Therapeutics stockholders are not entitled to appraisal rights with respect to the reverse stock split, and Critical Therapeutics will not independently provide stockholders with any such right.

***Material U.S. Federal Income Tax Consequences of the Reverse Stock Split***

The following discussion summarizes the material U.S. federal income tax consequences of the reverse stock split that are expected to apply generally to Critical Therapeutics stockholders as a result of the reverse stock split. This summary is based upon current provisions of the Code, existing Treasury Regulations and current administrative rulings and court decisions, all of which are subject to change and to differing interpretations, possibly with retroactive effect.

This summary only applies to a Critical Therapeutics stockholder that is a U.S. person, defined to include:

a citizen or resident of the United States;

a corporation created or organized in or under the laws of the United States, or any political subdivision thereof (including the District of Columbia);

an estate, the income of which is subject to U.S. federal income taxation regardless of its source;

a trust if either:

a court within the United States is able to exercise primary supervision over the administration of such trust and one or more U.S. persons have the authority to control all substantial decisions of such trust; or

the trust has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes; and

any other person or entity that is treated for U.S. federal income tax purposes as if it were one of the foregoing.

Any Critical Therapeutics stockholder other than a U.S. person as so defined is, for purposes of this discussion, a non-U.S. person. If a partnership holds Critical Therapeutics common stock, the tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. If you are a partner of a partnership holding Critical Therapeutics common stock, you should consult your tax advisor.

This summary assumes that Critical Therapeutics stockholders hold their shares of Critical Therapeutics common stock as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment). No attempt has been made to comment on all U.S. federal income tax consequences of the reverse stock split that may be relevant to particular holders, including holders:

who are subject to special treatment under U.S. federal income tax rules such as dealers in securities, financial institutions, non-U.S. persons, mutual funds, regulated investment companies, real estate investment trusts, insurance companies, or tax-exempt entities;

who acquired their shares in connection with stock option or stock purchase plans or in other compensatory transactions;

who hold their shares as qualified small business stock within the meaning of Section 1202 of the Code;

who hold their shares as part of an integrated investment such as a hedge or as part of a hedging, straddle or other risk reduction strategy; or

who do not hold their shares as capital assets.

In addition, the following discussion does not address the tax consequences of the reverse stock split under state, local and foreign tax laws or under the alternative minimum tax provisions of the Code. Furthermore, the following discussion does not address any of the tax consequences of transactions effectuated before, after or at the same time as the reverse stock split, whether or not they are in connection with the reverse stock split, including, without limitation, transactions in which shares of Critical Therapeutics common stock are acquired or disposed of.

**Accordingly, holders of Critical Therapeutics common stock are advised and expected to consult their own tax advisers regarding the U.S. federal income tax consequences of the reverse stock split to them in light of their personal circumstances and the consequences of the reverse stock split under state, local and foreign tax laws.**

Other than the cash payments for fractional shares discussed below, no gain or loss should be recognized by a Critical Therapeutics stockholder upon such stockholder's exchange of pre-split shares for post-split shares pursuant to the reverse stock split. The aggregate tax basis of the post-split shares received in the reverse stock split, including any fraction of a post-split share deemed to have been received, will be the same as the Critical Therapeutics stockholder's aggregate tax basis in the pre-split shares that are exchanged.

In general, Critical Therapeutics stockholders who receive cash upon the deemed sale of their fractional share interests in the post-split shares as a result of the reverse stock split will recognize gain or loss equal to the difference between their basis in the fractional share and the amount of cash received. The Critical Therapeutics stockholder's holding period for the post-split shares will include the period during which the stockholder held the pre-split shares surrendered in the reverse stock split.

Such gain or loss will be a capital gain or loss, and generally will constitute a long-term capital gain or loss if the stockholder's holding period in the stock exchanged is more than one year as of the closing date of the reverse stock split. Net capital gain (i.e., the excess of net long-term capital gain over net short-term capital loss) will be subject to tax at reduced rates for non-corporate stockholders who receive cash. The deductibility of capital losses is subject to various limitations for corporate and non-corporate holders.

For purposes of the above discussion of bases and holding periods, stockholders who acquired different blocks of stock at different times for different prices must calculate their gains and losses and holding periods separately for

each identifiable block of such stock exchanged in the reverse stock split.

Certain noncorporate Critical Therapeutics stockholders may be subject to backup withholding, at a rate of 28% for 2008, on cash received pursuant to the reverse stock split. Backup withholding will not apply, however, to a Critical Therapeutics stockholder who (1) furnishes a correct taxpayer identification number and certifies that the Critical Therapeutics stockholder is not subject to backup withholding on IRS Form W-9 or a substantially similar form, (2) provides a certification of foreign status on an appropriate Form W-8 or



successor form or (3) is otherwise exempt from backup withholding. If a Critical Therapeutics stockholder does not provide a correct taxpayer identification number on IRS Form W-9 or a substantially similar form, the Critical Therapeutics stockholder may be subject to penalties imposed by the IRS. Amounts withheld, if any, are generally not an additional tax and may be refunded or credited against the Critical Therapeutics stockholder's federal income tax liability, provided that the Critical Therapeutics stockholder furnishes the required information to the IRS.

**THE PRECEDING DISCUSSION IS INTENDED ONLY AS A SUMMARY OF CERTAIN U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE REVERSE STOCK SPLIT AND DOES NOT PURPORT TO BE A COMPLETE ANALYSIS OR DISCUSSION OF ALL OF THE REVERSE STOCK SPLIT'S POTENTIAL TAX EFFECTS. CRITICAL THERAPEUTICS STOCKHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE SPECIFIC TAX CONSEQUENCES TO THEM OF THE REVERSE STOCK SPLIT, INCLUDING TAX RETURN REPORTING REQUIREMENTS, AND THE APPLICABILITY AND EFFECT OF FEDERAL, STATE, LOCAL AND OTHER APPLICABLE TAX LAWS.**

***Vote Required; Recommendation of Board of Directors***

The affirmative vote of holders of a majority of the outstanding shares of Critical Therapeutics' common stock as of the record date for the special meeting is required for approval of Proposal 2.

A failure to submit a proxy card or vote at the special meeting, or an abstention, vote withheld or broker non-vote for Proposal 2 will have the same effect as a vote against the approval of Proposal 2.

**CRITICAL THERAPEUTICS' BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 2 TO AMEND CRITICAL THERAPEUTICS' CERTIFICATE OF INCORPORATION TO EFFECT THE REVERSE STOCK SPLIT.**

**Proposal 3: Approval of Name Change**

***General***

At the special meeting, holders of Critical Therapeutics common stock will be asked to approve the amendment of Critical Therapeutics' certificate of incorporation to change the name of the corporation from Critical Therapeutics to Cornerstone Therapeutics Inc. immediately following the effective time of the merger.

The primary reason for the corporate name change is that management believes this will allow for brand recognition of Cornerstone's products and product candidate pipeline following the consummation of the merger. Critical Therapeutics' management believes that the current name will no longer accurately reflect the business of the combined company and the mission of the combined company subsequent to the consummation of the merger. The text of the form of the proposed amendment to the Critical Therapeutics' certificate of incorporation is attached to this proxy statement/prospectus as *Annex C*.

Insofar as the proposed new corporate name will only reflect Cornerstone's business following the merger, the proposed name change and the amendment of Critical Therapeutics' certificate of incorporation, even if approved by the stockholders at the special meeting, will only be filed with the office of the Secretary of State of the State of Delaware and, therefore, become effective if the merger is consummated.

***Vote Required; Recommendation of Board of Directors***

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The affirmative vote of holders of a majority of the outstanding shares of Critical Therapeutics common stock as of the record date for the special meeting is required for approval of Proposal 3.

A failure to submit your proxy card or vote at the special meeting, or an abstention, vote withheld or broker non-vote for Proposal 3 will have the same effect as a vote against the approval of Proposal 3.

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 3 TO APPROVE THE NAME CHANGE.**

**Proposal 4: Approval of Possible Adjournment of the Special Meeting**

*General*

If Critical Therapeutics fails to receive a sufficient number of votes to approve Proposals 1, 2 or 3, Critical Therapeutics may propose to adjourn the special meeting, if a quorum is present, for a period of not more than 30 days for the purpose of soliciting additional proxies to approve Proposals 1, 2 or 3. Critical Therapeutics currently does not intend to propose adjournment at the special meeting if there are sufficient votes to approve Proposal Nos. 1, 2 and 3.

*Vote Required; Recommendation of Board of Directors*

The affirmative vote of the holders of a majority of the Critical Therapeutics common stock having voting power present in person or represented by proxy at the special meeting is required to approve the adjournment of the special meeting for the purpose of soliciting additional proxies to approve Proposals 1, 2 or 3.

A failure to submit a proxy card or vote at the special meeting, or an abstention, vote withheld or broker non-vote will have no effect on the outcome of Proposal 4.

**CRITICAL THERAPEUTICS BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT CRITICAL THERAPEUTICS STOCKHOLDERS VOTE FOR PROPOSAL 4 TO ADJOURN THE SPECIAL MEETING, IF NECESSARY, IF A QUORUM IS PRESENT, TO SOLICIT ADDITIONAL PROXIES IF THERE ARE NOT SUFFICIENT VOTES IN FAVOR OF PROPOSALS 1, 2 OR 3.**

## CRITICAL THERAPEUTICS BUSINESS

### Overview

Critical Therapeutics is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory diseases, as well as other inflammatory diseases linked to the body's inflammatory response. Critical Therapeutics' two marketed products are ZYFLO CR, which the FDA approved in May 2007, and ZYFLO, which the FDA approved in 1996, for the prevention and chronic treatment of asthma in adults and children 12 years of age or older. Critical Therapeutics licensed from Abbott exclusive worldwide rights to ZYFLO CR, ZYFLO and other formulations of zileuton for multiple diseases and conditions. Critical Therapeutics began selling ZYFLO CR in the United States in September 2007 and began selling ZYFLO in the United States in October 2005. In addition, Critical Therapeutics is developing zileuton injection.

In September 2007, Critical Therapeutics' sales force and the sales force of its co-promotion collaborator, DEY, began actively promoting ZYFLO CR and ceased actively promoting ZYFLO. Critical Therapeutics ceased manufacturing and supplying ZYFLO in February 2008, but it expects to resume the supply of ZYFLO in August 2008 to help manage the potential impact to patients of supply chain issues for ZYFLO CR. Critical Therapeutics recently completed a Phase I clinical trial to examine the pharmacokinetic and pharmacodynamic profile of the R(+) isomer of zileuton to determine if there are potential dosing improvements for patients from this isomer. In addition, Critical Therapeutics is developing zileuton injection initially for use in emergency room or urgent care centers for patients who suffer acute exacerbations of asthma. In June 2008, Critical Therapeutics announced results from its Phase II clinical trial with zileuton injection in patients with chronic, stable asthma. Critical Therapeutics intends to initiate a process to seek to enter into a collaboration agreement for the future clinical development and commercialization of zileuton injection.

On March 13, 2007, Critical Therapeutics entered into an agreement with DEY, under which Critical Therapeutics and DEY agreed to jointly promote ZYFLO and ZYFLO CR. On June 25, 2007, Critical Therapeutics entered into a definitive agreement with DEY to jointly promote DEY's product PERFOROMIST for the treatment of COPD. In October 2007, Critical Therapeutics announced that it had commercially launched PERFOROMIST with DEY. On July 2, 2008, Critical Therapeutics provided notice to DEY that Critical Therapeutics had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

Critical Therapeutics has been conducting preclinical work in its alpha-7 nicotinic acetylcholine receptor program, or alpha-7 program. Critical Therapeutics believes the successful development of a small molecule product candidate targeting the alpha-7 nicotinic acetylcholine receptor, or alpha-7 receptor, could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma and rheumatoid arthritis. Based on preclinical studies, Critical Therapeutics selected lead and backup molecules for evaluation in good laboratory practices, or GLP, toxicology studies. Provided the data are supportive and sufficient resources are available, Critical Therapeutics believes that an IND could be filed in 2009. In addition, Critical Therapeutics plans to seek collaborations with other pharmaceutical companies for its alpha-7 program to develop and commercialize possible product candidates in multiple development opportunities that may exist within this program prior to the initiation of human clinical trials. Critical Therapeutics licensed to IMI patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. This license agreement specifically excludes from the licensed field pharmacological modulation of the alpha-7 receptor.

Critical Therapeutics has been collaborating with MedImmune on the development of monoclonal antibodies directed toward a cytokine called HMGB1, which Critical Therapeutics believes may be an important target for the

development of products to treat diseases mediated by the body's inflammatory response. In addition, Critical Therapeutics has been collaborating with Beckman Coulter on the development of a diagnostic directed toward measuring HMGB1 in the bloodstream.

Critical Therapeutics was incorporated in Delaware on July 14, 2000 as Medicept, Inc. and changed its name to Critical Therapeutics in March 2001. Critical Therapeutics completed an initial public offering of its common stock in June 2004, and its common stock is currently traded on The NASDAQ Capital Market.

### **Proposed Merger with Cornerstone**

Until the closing of the proposed merger with Cornerstone, Critical Therapeutics expects to continue its commercial and development activities in accordance with its existing business strategy with an increased focus on managing its cash position. The description of Critical Therapeutics' business set forth in this proxy statement/prospectus does not reflect any changes to Critical Therapeutics' business that may occur if it consummates the proposed merger with Cornerstone. For instance, the combined company's clinical and preclinical pipeline will include a number of product candidates. The combined company is expected to implement a strategic review of its product development pipeline. Following the strategic review, the combined company may seek to maximize the value of any non-core programs through out-licensing, divestiture or spin-off transactions.

### **Critical Therapeutics' Product Pipeline**

The following table sets forth the current status of Critical Therapeutics' products and product candidates in development and Critical Therapeutics' research and development programs:

\* Being developed with MedImmune under an exclusive license and collaboration agreement. Diagnostic assays directed towards HMGB1 are being developed with Beckman Coulter under a license agreement.

### **Zileuton**

In 2003, Critical Therapeutics acquired from Abbott exclusive worldwide rights to develop and market ZYFLO CR and other formulations of zileuton for multiple diseases and conditions. In 2004, Critical Therapeutics acquired from Abbott exclusive worldwide rights to develop and market ZYFLO. The FDA approved Critical Therapeutics' supplemental new drug application, or sNDA, for ZYFLO on September 28, 2005, and Critical Therapeutics began selling ZYFLO in the United States in October 2005. Critical Therapeutics ceased manufacturing and supplying ZYFLO in February 2008, but expects to resume supply of ZYFLO in August 2008 to help manage the potential impact to patients of supply chain issues for ZYFLO CR. The FDA approved the NDA for ZYFLO CR on May 30, 2007, and Critical Therapeutics subsequently launched ZYFLO CR in the United States on September 27, 2007.

Zileuton blocks the activity of the 5-lipoxygenase enzyme, which is the main enzyme responsible for formation of a family of lipids known as leukotrienes. There are many different leukotrienes, and the mechanism of action of ZYFLO CR and ZYFLO blocks production of the entire leukotriene family.

Leukotrienes are in part responsible for the inflammatory response associated with asthma and are known to cause many of the biological effects that contribute to inflammation, mucus production and closing of the lung airways of asthmatic patients. Leukotrienes are also implicated in the disturbance of normal lung airway function in other diseases, including COPD. ZYFLO CR and ZYFLO are the only FDA-approved leukotriene synthesis inhibitors for the prevention and chronic treatment of asthma in adults and children 12 years of age and older.

### ***Therapeutic Opportunity***

Asthma is a chronic respiratory disease characterized by the narrowing of the lung airways, making breathing difficult. An asthma attack leaves the victim short of breath as the airways become constricted and inflamed. The National Center for Health Statistics estimates that in 2005 approximately 22.2 million people in the United States had asthma and approximately 12.2 million people in the United States had asthma attacks. Severe asthma attacks can be life threatening. The National Center for Health Statistics estimates that in 2005 approximately 1.8 million hospital emergency room visits in the United States involved asthma attacks and approximately 488,594 hospital discharges were attributable to asthma.

There is no one ideal treatment for asthma, and there is no cure. Currently, patients are treated with a combination of products that are designed primarily to manage their disease symptoms by opening the airways in the lungs and reducing inflammation. Typical treatments include bronchodilatory drugs, such as Serevent<sup>®</sup>, LTRAs, such as Singulair<sup>®</sup>, inhaled corticosteroids, such as Flovent<sup>®</sup> and combination products such as Advair<sup>®</sup>, which is a combination of an inhaled corticosteroid and a long-acting bronchodilator. Critical Therapeutics believes many prescribing physicians are dissatisfied with the treatment options available for uncontrolled asthmatic patients due to the inability of these treatments to control symptoms reliably. A recent study, titled *Real-world Evaluation of Asthma Control and Treatment (REACT): Findings from a National Web-based Survey* and published in *The Journal of Allergy & Clinical Immunology*, stated that nearly 55% of all moderate to severe asthmatics remain uncontrolled despite being treated with asthma medications.

Critical Therapeutics believes that many patients with asthma may benefit from therapy with ZYFLO CR or ZYFLO. ZYFLO CR and ZYFLO actively inhibit the main enzyme responsible for the production of a broad spectrum of lipids responsible for the symptoms associated with asthma, including all leukotrienes. Critical Therapeutics is marketing ZYFLO CR and ZYFLO as treatments for asthma patients who do not gain adequate symptomatic control from other currently available medications.

### ***Zileuton Product Development***

#### ***ZYFLO: The Immediate-Release Formulation of Zileuton***

ZYFLO and ZYFLO CR are the only leukotriene synthesis inhibitor drugs to be approved for marketing by the FDA. In 1996, ZYFLO was approved by the FDA as an immediate-release, four-times-a-day tablet for the prevention and chronic treatment of asthma in adults and children 12 years of age and older. ZYFLO was first launched in the United States in 1997. The FDA approved Critical Therapeutics' sNDA for ZYFLO on September 28, 2005, and Critical Therapeutics began selling ZYFLO in the United States in October 2005. Critical Therapeutics recognized revenue from sales of ZYFLO of \$711,000 in the first quarter of 2008, \$8.7 million in 2007, \$6.6 million in 2006 and \$387,000 in 2005. Critical Therapeutics recognized revenue from sales of ZYFLO CR of \$2.6 million in the first quarter of 2008 and \$2.3 million in 2007. The full clinical development program for ZYFLO consisted of 21 safety and efficacy trials in an aggregate of approximately 3,000 patients with asthma. FDA approval was based on pivotal three-month and six-month safety and efficacy clinical trials in 774 asthma patients. The pivotal trials compared patients taking ZYFLO and their rescue bronchodilators as needed to patients taking placebo and rescue bronchodilators as needed. The results of the group taking ZYFLO and their rescue bronchodilators showed:

rapid and sustained improvement for patients over a six-month period in objective and subjective measures of asthma control;



reduction of exacerbations and need for either bronchodilatory or steroid rescue medications; and

acute bronchodilatory effect within two hours after the first dose.

Critical Therapeutics' post hoc analysis of the data suggested there was a greater airway response benefit in asthma patients with less than 50% of expected airway function, and a six-fold decrease in the need for steroid rescue medication in these patients compared to placebo.

In these placebo-controlled clinical trials, 1.9% of patients taking ZYFLO experienced an increase in the liver enzyme ALT greater than three times the level normally seen in the bloodstream compared to 0.2% of patients receiving placebo. These enzyme levels resolved or returned towards normal in approximately 50% of the patients who continued therapy and all of the patients who discontinued the therapy.

In addition, prior to FDA approval, a long-term, safety surveillance trial was conducted in 2,947 patients. In this safety trial, 4.6% of patients taking ZYFLO experienced ALT levels greater than three times the level normally seen in the bloodstream compared to 1.1% of patients receiving placebo. In 61.0% of the patients with ALT levels greater than three times the level normally seen in the bloodstream, the elevation was seen in the first two months of dosing. After two months of treatment, the rate of ALT levels greater than three times the level normally seen in the bloodstream stabilized at an average of 0.3% per month for patients taking a combination of ZYFLO and their usual asthma medications compared to 0.11% per month for patients taking a combination of placebo and their usual asthma medications. This trial also demonstrated that ALT levels returned to below two times the level normally seen in the bloodstream in both the patients who continued and those who discontinued the therapy. The overall rate of patients with ALT levels greater than three times the level normally seen in the bloodstream was 3.2% in the approximately 5,000 patients who received ZYFLO in placebo-controlled and open-label trials combined. In these trials, one patient developed symptomatic hepatitis with jaundice, which resolved upon discontinuation of therapy, and three patients developed mild elevations in bilirubin.

After reviewing the data from these trials, the FDA approved ZYFLO in 1996 on the basis of the data submitted, and Critical Therapeutics is not aware of any reports of ZYFLO being directly associated with serious irreversible liver damage in patients treated with ZYFLO since its approval.

#### *ZYFLO CR: The Extended-Release Formulation of Zileuton*

Critical Therapeutics commercially launched ZYFLO CR in September 2007, following its approval by the FDA in May 2007. Critical Therapeutics believes ZYFLO CR offers a more convenient regimen for patients because of its twice-daily, two tablets per dose dosing regimen, as compared to ZYFLO's four-times daily dosing regimen, which Critical Therapeutics believes may increase patient drug compliance. Abbott completed Phase III clinical trials for this formulation in asthma, but did not submit an NDA. Critical Therapeutics submitted the NDA for ZYFLO CR to the FDA based on safety and efficacy data generated from two completed Phase III clinical trials, a three-month efficacy trial and a six-month safety trial, each of which was completed by Abbott. The study reports prepared by Abbott for these clinical trials showed:

In a three-month pivotal efficacy trial, in which 397 patients received either ZYFLO CR or placebo, patients taking ZYFLO CR demonstrated statistically significant improvements over placebo in objective measures of asthma control, such as mean forced expiratory volume in one second, or FEV<sub>1</sub>. In the trial, patients taking ZYFLO CR showed a reduced need for bronchodilatory drugs as a rescue medication to alleviate uncontrolled symptoms. In this trial, 2.5% of the patients taking ZYFLO CR experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream, compared to 0.5% of the patients taking placebo.

In a six-month safety trial, in which 706 patients received either a combination of ZYFLO CR and their usual asthma medications or a combination of placebo and their usual asthma medications, 1.78% of the patients taking ZYFLO CR and their usual asthma medications experienced ALT levels greater than or equal to three times the level normally seen in the bloodstream, compared to 0.65% of the patients taking placebo and their usual asthma medications.

To be able to rely on the results of Abbott's pivotal clinical trials, Critical Therapeutics conducted two comparative bioavailability studies intended to show that the pharmacokinetic profile of ZYFLO CR tablets that Critical Therapeutics manufactured was similar to the pharmacokinetic profile of the ZYFLO CR tablets previously manufactured by Abbott and used in Abbott's clinical trials. Critical Therapeutics conducted both a single-dose and a multiple-dose pharmacokinetic study. The studies assessed the pharmacokinetics of ZYFLO CR in volunteers under both fed and fasting conditions.

Critical Therapeutics entered into an agreement in March 2007 with DEY under which Critical Therapeutics and DEY jointly co-promote ZYFLO CR and ZYFLO.

### *Zileuton Injection*

Critical Therapeutics is developing zileuton injection for use as an adjunctive treatment for patients with acute exacerbations of asthma. Critical Therapeutics believes acute exacerbations of asthma are a significant unmet medical need that occur in asthma patients who are poorly controlled on their existing medications. According to the American Lung Association, in 2005, approximately 1.8 million hospital emergency room visits in the United States involved asthma attacks and approximately 488,594 hospital discharges were attributable to asthma. Critical Therapeutics is developing zileuton injection as a new treatment option for acute asthma patients in the emergency department that can be added to existing therapies in order to improve pulmonary function by controlling both bronchospasm and pulmonary inflammation through zileuton's mechanism of action, leukotriene synthesis inhibition.

Currently, most patients suffering severe asthma attacks are treated with bronchodilators inhaled via a nebulizer, typically for 20 minutes or more. Nebulizers attempt to restore airway function by delivering the bronchodilatory drug directly into the lungs. However, the patient's ability to get the drug into his or her lungs may be impaired by his or her inability to breathe efficiently due to the severe asthma attack. Clinical data demonstrate that zileuton exhibits its maximum effect on lung function when the blood drug concentration reaches its peak level and that the effect can be achieved after a single oral dose of zileuton. Critical Therapeutics believes that an injectable formulation of zileuton that would deliver zileuton directly to the bloodstream would have a rapid onset of action, reaching peak blood concentration within minutes of the injection. Critical Therapeutics believes that this rapid delivery of the drug to the patient's bloodstream may lead to more rapid improvements in symptoms, and potentially reduce the number of hospital admissions of patients arriving in the emergency room suffering from a severe asthma attack.

In August 2006, Critical Therapeutics announced results from a Phase I/II clinical trial with zileuton injection in chronic stable asthmatics. The trial included measurements to detect evidence of improvement in lung function. The multi-center, double-blind, placebo-controlled trial enrolled 60 patients with a mean FEV<sub>1</sub> of 63 percent of predicted normal at baseline and a mean age of 40 years. Patients enrolled in the trial were randomized into four escalating dose groups, 75 mg, 150 mg, 300 mg and 600 mg, and received one infusion of either zileuton injection or placebo. Each of the four dose groups enrolled 15 patients, of whom 12 received zileuton injection and three received placebo. All 60 patients who were randomized completed the trial.

Patients in each of the four zileuton injection cohorts showed a greater mean percentage improvement in FEV<sub>1</sub> than patients in the placebo group when measured at 10, 30 and 60-minute intervals after dosing. The 300 mg dose was predicted to approximate the blood level exposure of the currently approved immediate-release oral dose of ZYFLO. In this trial, the 300 mg dose group showed a mean improvement in FEV<sub>1</sub> from baseline of 13.7 percent at 60 minutes after dosing. In addition, zileuton injection was well tolerated at all doses tested with no serious adverse events reported in the trial.

In June 2008, Critical Therapeutics announced top-line results from a Phase II clinical trial with zileuton injection in chronic stable asthmatics. The trial was designed to explore the pulmonary function profile, safety, tolerability and pharmacokinetic profile of zileuton injection. The multi-center, double-blind, placebo-controlled, three-period cross-over trial enrolled 36 patients with stable, moderate-to-severe asthma and a FEV<sub>1</sub> of 40 percent to 80 percent of predicted normal. In this trial, patients received a single dose of 150 mg or 300 mg of zileuton injection or placebo, administered via a peripheral intravenous, or IV, catheter at a

standard continuous rate. The trial measured pulmonary function using FEV<sub>1</sub> at multiple time points over the first hour then hourly until six hours after dosing.

Zileuton injection, at both dose levels, was well tolerated in all 36 patients and there were no serious adverse events reported. Patients receiving each of the two zileuton injection dose levels showed a numerically greater mean percentage improvement in FEV<sub>1</sub> from baseline than patients receiving placebo; however, the results were not statistically significant compared to placebo.

The mean percentage improvement in FEV<sub>1</sub> from baseline was evident from the first measurement time point of 10 minutes after dosing and was maintained for at least four hours. Critical Therapeutics believes that the variability in baseline levels of FEV<sub>1</sub> seen within individual patients across the three dosing regimens often resulted in higher than expected baseline lung function, which did not provide an opportunity to achieve a meaningful improvement in lung function that could approach statistical significance. Exploratory analyses conducted on the trial data indicate that patients with a baseline FEV<sub>1</sub> less than or equal to 65% of predicted normal responded better to zileuton treatment.

Critical Therapeutics believes that these exploratory analyses and the tolerability of zileuton injection may support a clinical trial in an acute population as a potential next step in the development process. Critical Therapeutics intends to initiate a process to seek to enter into a collaboration agreement for the future clinical development and commercialization of zileuton injection.

### ***Commercialization Strategy***

As of June 30, 2008, Critical Therapeutics has a respiratory sales force of approximately 29 representatives who are focused on promoting ZYFLO CR and PERFOROMIST to prescribing physicians in major markets across the United States. Critical Therapeutics is seeking to increase utilization of ZYFLO CR and ZYFLO by prescribing physicians.

In March 2007, Critical Therapeutics entered into a co-promotion agreement with DEY under which Critical Therapeutics and DEY agreed to jointly promote ZYFLO and, after approval by the FDA, ZYFLO CR. DEY has a respiratory sales force consisting of approximately 200 clinical sales representatives as of May 31, 2008. Under the co-promote agreement, DEY is required to provide a specified number of details per month for ZYFLO CR, in the second position, to office-based physicians and other health care professionals, including a minimum number of details delivered to respiratory specialists, such as allergists and pulmonologists. Under the co-promotion agreement, Critical Therapeutics has agreed to provide a specified number of details per month for ZYFLO CR in the first position. From 2008 through 2010, Critical Therapeutics and DEY each have agreed to contribute 50 percent of out-of-pocket promotion expenses for ZYFLO CR that are accrued or paid to third-parties and approved by a joint commercial committee. Critical Therapeutics was responsible for third-party promotion costs during 2007.

Critical Therapeutics believes that there is a market opportunity for the use of ZYFLO CR as an add-on therapy option for patients whose asthma symptoms are not adequately controlled with the use of inhaled corticosteroids and other conventional therapies, including LTRAs and LABAs. Critical Therapeutics' belief is based on information that it has gathered through extensive direct interactions and market research with respiratory specialists, including allergists and pulmonologists and primary care physicians, such as:

- more than two years of in-depth interaction between Critical Therapeutics' medical science liaisons with key opinion leaders in the treatment of respiratory diseases, including asthma;

- more than two years of interaction between Critical Therapeutics' sales force and respiratory specialists who treat asthma; and

qualitative and quantitative market research that it has conducted since 2004.

Critical Therapeutics continues to conduct research to refine its messaging, positioning and understanding of prescriber attitudes and perceptions of ZYFLO CR.

Critical Therapeutics is positioning ZYFLO CR as an alternative treatment for asthma patients who do not gain adequate control of their symptoms with other currently available medications, including inhaled corticosteroids, long-acting beta agonists and LTRAs. Critical Therapeutics is promoting ZYFLO CR to

respiratory specialists, managed care decision makers and some primary care physicians who treat large volumes of asthma patients. As part of its marketing strategy, Critical Therapeutics attempts to educate key opinion leaders and physicians on the scientific data that differentiates the mechanism of action of ZYFLO CR from other asthma treatments and emphasize clinical data that show safety and efficacy for ZYFLO CR in asthma.

Critical Therapeutics is also attempting to maximize patient and physician access to ZYFLO CR by addressing the position of ZYFLO CR on managed care formularies. Critical Therapeutics believes that in many managed care formularies ZYFLO CR has been positioned on third-tier status, which requires the highest co-pay for patients prescribed the product. In some cases, MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for ZYFLO CR.

In June 2007, the National Heart Lung, and Blood Institute, or NHLBI, released an updated version of the Guidelines for the Diagnosis and Management of Asthma. In these guidelines, zileuton is specifically mentioned in steps three and four in the treatment spectrum as an alternative option in the treatment of asthma. This is the first time zileuton has been mentioned in these guidelines, and Critical Therapeutics believes this may provide additional scientific credibility to ZYFLO CR in the marketplace. In addition to the changes in the recommended treatment protocol for asthma, the updated guidelines continue to support the transition to discussing asthmatic patients in terms of their level of control rather than their severity level.

Since the commercial launch of ZYFLO CR in September 2007, Critical Therapeutics has experienced growth in overall prescription volume and the number of physicians prescribing ZYFLO CR, and it believes this growth is due to the greater market acceptance of the twice-daily dosing of ZYFLO CR compared to the four-times daily immediate-release formulation of ZYFLO.

Critical Therapeutics is exploring the therapeutic benefits of zileuton in treating a range of diseases and conditions, including acute asthma exacerbations and COPD. Critical Therapeutics is aware, for instance, of clinical data available in publications of clinical trials and individual patient case studies that indicate zileuton has shown efficacy in the treatment of nasal polyps. The NIH sponsored and is funding a clinical trial to evaluate whether using ZYFLO to treat patients admitted to the hospital with acute exacerbations of COPD will shorten their hospital stay. The clinical trial began in September 2007 and is being conducted by the COPD Clinical Research Network. In each case, if Critical Therapeutics develops zileuton for one of these diseases or conditions, it will need to commence clinical development programs to generate sufficient information to obtain regulatory approval.

#### ***R(+)* Isomer of Zileuton**

In April 2008, Critical Therapeutics announced the results of a Phase I clinical trial to assess the safety and tolerability of an oral single dose of the R(+) isomer of zileuton. R(+) zileuton combined in equal proportion with its mirror image isomer, S(-) zileuton, comprise racemic zileuton. The trial was designed to examine the safety, tolerability, pharmacokinetic and pharmacodynamic profile of the R(+) isomer of zileuton in healthy subjects. The randomized, open-label, single dose, single center, two-period crossover trial enrolled 12 participants. Each trial participant received both 100 mg and 300 mg doses of the R(+) isomer of zileuton in a randomized, crossover design. Both dose levels of R(+) zileuton were well tolerated with no serious adverse events or clinical safety concerns reported in this trial. Pharmacokinetic data obtained for R(+) zileuton, dosed alone to humans for the first time, exhibited dose proportionality and matched historical data obtained for R(+) zileuton following equivalent doses of racemic zileuton in earlier clinical trials. The pharmacokinetic profile of R(+) zileuton obtained in this trial confirmed that it constitutes approximately two-thirds of the plasma exposure observed with racemic zileuton and is the more persistent isomer of zileuton.

Critical Therapeutics was not able to gain any pharmacodynamic data from this trial. In previous in vitro preclinical studies conducted by Critical Therapeutics with human whole blood, R(+) zileuton exhibited higher potency for leukotriene synthesis inhibition than S(-) zileuton indicating that this enantiomer exhibits a more prolonged plasma pharmacokinetic exposure profile. Critical Therapeutics believes that these features may



offer the opportunity for the development of a product candidate with a reduced tablet size or less frequent dose administration.

### **Critical Care: The Inflammatory Response**

Critical Therapeutics is developing product candidates directed towards reducing the potent inflammatory response that it believes is associated with the pathology, morbidity and, in some cases, mortality in many acute and chronic diseases. Critical Therapeutics' early-stage product development programs center on controlling the production of potent inflammatory mediators that play a key role in regulating the body's immune system. The cascading release of the inflammatory mediators that occurs in many disease settings leads, in large part, to the uncontrolled, pathologic inflammation that can occur in trauma, infection and autoimmune and allergic diseases. Critical Therapeutics believes that this cascade plays an important role in the severe inflammatory response seen in:

acute diseases and conditions that lead to admission to the intensive care unit, or ICU, such as sepsis and septic shock; and

acute exacerbations of chronic diseases that frequently lead to hospitalization, such as asthma, lupus and rheumatoid arthritis.

In the setting of severe infection, trauma, severe bleeding or a lack of oxygen to the major organs of the body, the overproduction of inflammatory mediators, including cytokines, can lead to organ failure, tissue destruction and, eventually, death. When cytokine levels become elevated, an excessive inflammatory response occurs that may potentially result in damage to vital internal organs and, in the most severe cases, multiple organ failure and death. Many previous therapies directed at cytokines, such as tumor necrosis factor alpha, or TNF alpha, in acute diseases have failed in clinical development.

The individual programs within Critical Therapeutics' portfolio, while targeted toward the inflammatory response, exert their effects through different mechanisms of action. These programs include:

an alpha-7 program directed towards a receptor that Critical Therapeutics believes regulates the release of the cytokines that play a fundamental role in the inflammatory response, including TNF alpha, in response to an inflammatory stimulus; and

an HMGB1 program directed towards the pro-inflammatory protein HMGB1.

These programs are described in more detail below.

#### ***Alpha-7 Program***

Stimulation of the vagus nerve, a nerve that links the brain with the major organs of the body, causes the release of a chemical neurotransmitter called acetylcholine. Acetylcholine has been shown to inhibit the release of cytokines that play a fundamental role in the inflammatory response, including TNF alpha. Research indicates that acetylcholine exerts anti-inflammatory activity by stimulating alpha-7 receptor on cells involved in the inflammatory process.

Historically, a number of companies have focused on the alpha-7 receptor target for the treatment of central nervous system diseases. Critical Therapeutics believes the discovery of the role of this receptor in inflammation has led to a new opportunity for the development of products to treat diseases in which inflammation plays a role. Critical Therapeutics is undertaking a program to develop a small molecule product candidate that inhibits the inflammatory response by stimulating the alpha-7 receptor on human inflammatory cells.

*Therapeutic Opportunity*

Critical Therapeutics' successful development of a product candidate targeting the alpha-7 receptor could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma, rheumatoid arthritis and Crohn's disease. Critical

Therapeutics believes the previous work on the alpha-7 receptor will assist the discovery of new, peripherally acting drugs that selectively stimulate the alpha-7 receptor. Critical Therapeutics believes a drug candidate taken orally could have a strong market position against current injectable anti-TNF alpha biological therapies, particularly if it avoids the potential immunological response to therapy, which is a known risk with antibody products.

#### *Development Strategy*

Critical Therapeutics is currently completing preclinical evaluations of proprietary small molecule product candidates in its alpha-7 program. Critical Therapeutics has seen positive results with its molecules in animal models of allergic lung inflammation and acute lung injury, including models using alpha-7 knock-out mice. Critical Therapeutics believes the initial results support the concept that the alpha-7 receptor plays an important role in modulating the severity of inflammation in these models and that Critical Therapeutics' molecules work by stimulating this receptor. Critical Therapeutics has selected both a lead and a backup molecule, and it believes both have shown promising preclinical pharmacology and non-GLP toxicology results. Critical Therapeutics moved the lead molecule into GLP toxicology evaluations in 2008. Provided the data are supportive and sufficient resources are available, Critical Therapeutics believes that an investigational new drug application, or IND, could be filed in 2009. Critical Therapeutics plans to seek a collaborator for its alpha-7 program to develop and commercialize possible product candidates in multiple development opportunities that may exist for this program prior to initiation of human clinical trials.

#### ***HMGB1 Program***

Critical Therapeutics is evaluating mechanisms to prevent HMGB1 from effecting its role in inflammation-mediated diseases. HMGB1 has been identified as a potential late mediator of inflammation-induced tissue damage. Unlike other previously identified cytokines, such as interleukin-1 and TNF alpha, HMGB1 is expressed much later in the inflammatory response and persists at elevated levels in the bloodstream for a longer time period. Critical Therapeutics believes, therefore, that HMGB1 is a unique target for the development of products to treat inflammation-mediated diseases.

In 2003, Critical Therapeutics entered into an exclusive license and collaboration agreement with MedImmune to jointly develop and commercialize therapeutic products directed towards blocking the pro-inflammatory activity of HMGB1. In January 2005, Critical Therapeutics entered into a collaboration with Beckman Coulter to develop a diagnostic assay that could be used to identify which patients have elevated levels of HMGB1 and would, therefore, be most likely to respond to anti-HMGB1 therapy.

As part of the MedImmune collaboration, the research programs are currently aimed at generating antibodies that can neutralize circulating HMGB1 prior to it binding to its receptor. Fully human antibodies directed towards HMGB1, including fully human antibodies identified as part of the MedImmune collaboration, are currently in preclinical development. In December 2005, MedImmune agreed that proof of concept had been achieved for two preclinical models with human anti-HMGB1 monoclonal antibodies. These antibodies are now undergoing further evaluation with the goal of selecting candidates for use in clinical testing.

#### *Therapeutic Opportunity*

Critical Therapeutics believes that HMGB1's delayed and prolonged expression offers a new target for the development of products for acute diseases that can result in multiple organ failure, including sepsis and septic shock, and acute exacerbations of chronic diseases associated with the inflammatory response mediated by cytokines, such as rheumatoid arthritis and lupus.

Sepsis is the body's systemic inflammatory response to infection or trauma. In animal models relating to septic shock, monoclonal antibodies targeting HMGB1 were successful in significantly reducing the mortality rate associated with these models. To date, limited clinical investigations have identified that patients with sepsis have elevated levels of HMGB1 in their bloodstream, compared to normal individuals, who do not have detectable levels of HMGB1 in their bloodstream. The elevated HMGB1 levels appeared to be greatest in the patients who subsequently died as a result of their disease.

Similar treatment opportunities also exist with other diseases that include an HMGB1 component, such as rheumatoid arthritis. Elevated levels of HMGB1 have been observed in the synovial fluid in the joints of rheumatoid arthritis patients, and positive symptom responses have been achieved in animal models of rheumatoid arthritis with anti-HMGB1 therapy. Human monoclonal antibodies jointly generated by the collaboration with MedImmune have demonstrated promising activity in assays and animal models with relevance to clinical arthritis and lupus.

### *Clinical Strategy*

Critical Therapeutics has generated a number of fully human antibodies that bind to HMGB1 and that are active in vitro and in vivo. A number of these antibodies have demonstrated a dose-dependent benefit on survival in a mouse model of sepsis and a reduction in clinical arthritis symptoms in mouse and rat models of arthritis. In some of these tests, the monoclonal antibodies were administered in a treatment model after disease onset, as opposed to the preventive model in which the drug is administered before disease onset.

The research phase of the collaboration with MedImmune has ended and, under the collaboration agreement, MedImmune is responsible for conducting programs necessary to advance potential product candidates into Phase I clinical trials. As of June 30, 2008, no decision to select a clinical candidate has been made.

### **Collaborations**

#### ***Zileuton Co-Promotion Agreement with DEY***

On March 13, 2007, Critical Therapeutics entered into an agreement with DEY under which Critical Therapeutics and DEY agreed to jointly co-promote ZYFLO and, after approval by the FDA, ZYFLO CR. Under the co-promotion and marketing services agreement, Critical Therapeutics granted DEY an exclusive right and license or sublicense, under patent rights controlled by Critical Therapeutics, to promote and detail ZYFLO and ZYFLO CR in the United States, together with Critical Therapeutics and its affiliates, for asthma and, subject to FDA approval, other respiratory conditions.

Both Critical Therapeutics and DEY have agreed to use diligent efforts to promote the applicable products in the United States during the term of the co-promotion agreement. In addition, DEY has agreed to provide a minimum number of details per month for ZYFLO CR in the second position to office-based physicians and other health care professionals, including a minimum number of details delivered to respiratory specialists, such as allergists and pulmonologists. Critical Therapeutics has agreed to provide a minimum number of details per month for ZYFLO CR in the first position. From 2008 through 2010, Critical Therapeutics and DEY each have agreed to contribute 50% of approved out-of-pocket promotional expenses for ZYFLO CR that are accrued or paid to third-parties. Critical Therapeutics and DEY each have agreed to contribute a minimum of \$3.0 million per year for these promotional expenses. Critical Therapeutics was responsible for third-party promotional costs during 2007.

Under the co-promotion agreement, DEY paid Critical Therapeutics in 2007 a non-refundable upfront payment of \$3.0 million upon signing the co-promotion agreement, non-refundable milestone payments of \$4.0 million following approval by the FDA of the NDA for ZYFLO CR and \$5.0 million following commercial launch of ZYFLO CR. Under the co-promotion agreement, Critical Therapeutics records all quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, up to \$1.95 million. Critical Therapeutics pays DEY a portion of quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, in excess of \$1.95 million. From the date DEY began detailing ZYFLO through the commercial launch of ZYFLO CR in September 2007, Critical Therapeutics agreed to pay DEY 70% of quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, in excess of \$1.95 million. Following the commercial launch of ZYFLO CR in September 2007 through December 31, 2010, Critical Therapeutics has agreed to pay DEY 35% of quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties,

in excess of \$1.95 million. From January 1, 2011 through December 31, 2013, Critical Therapeutics has agreed to pay DEY 20% of quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, in excess of \$1.95 million.

The co-promotion agreement has a term expiring on December 31, 2013, which may be extended upon mutual agreement by the parties. Beginning September 25, 2010, either party may terminate the co-promotion agreement with six-months advance written notice. In addition, DEY has the right to terminate the co-promotion agreement with two-months prior written notice if ZYFLO CR cumulative net sales for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than \$25 million. Each party has the right to terminate the co-promotion agreement upon the occurrence of a material uncured breach by the other party.

DEY has agreed not to manufacture, detail, sell, market or promote any product containing zileuton as one of the APIs for sale in the United States until the later of one year after expiration or termination of the co-promotion agreement and March 15, 2012. However, if an AB-rated generic product to ZYFLO CR is introduced, DEY would not be subject to these non-competition obligations, and DEY will have the exclusive right to market the authorized generic version of ZYFLO CR. DEY also will not be subject to these non-competition obligations if DEY terminates the co-promotion agreement either because ZYFLO CR cumulative net sales for any four consecutive calendar quarters after commercial launch of ZYFLO CR are less than \$25 million or upon the occurrence of a material uncured breach by Critical Therapeutics.

A joint commercial committee with two members from Critical Therapeutics and two members from DEY oversees co-promotion activities under the co-promotion agreement. The co-promotion agreement provides that the joint commercial committee will make decisions by unanimous agreement, with disagreements being referred for resolution by the Chief Executive Officer of each party and further disputes being subject to non-binding mediation.

#### ***PERFOROMIST Co-Promotion Agreement with DEY***

On June 25, 2007, Critical Therapeutics entered into a co-promotion agreement with DEY relating to PERFOROMIST, DEY's product for the treatment of COPD. Under the co-promotion agreement, DEY granted Critical Therapeutics a right and license or sublicense to promote and detail PERFOROMIST in the United States, together with DEY. The co-promotion agreement supersedes a binding letter agreement between DEY and Critical Therapeutics dated March 13, 2007 relating to the co-promotion of PERFOROMIST. On July 2, 2008, Critical Therapeutics provided notice to DEY that Critical Therapeutics had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

Both Critical Therapeutics and DEY have agreed to use diligent efforts to promote PERFOROMIST in the United States during the term of the co-promotion agreement. In addition, Critical Therapeutics has agreed to provide a minimum number of primary detail equivalents per month for PERFOROMIST to a specified group of office-based physicians and other health care professionals. Critical Therapeutics is responsible for its own sales force expenses, including the cost of promotional materials used by its sales force. Under this co-promotion agreement, DEY has agreed to pay Critical Therapeutics a co-promotion fee under a calculation based on retail sales of PERFOROMIST.

During the term of this co-promotion agreement and for a period of one year after the expiration or termination of the co-promotion agreement, Critical Therapeutics has agreed not to manufacture, detail, sell, market or promote in the United States any product containing forms or derivatives of formoterol, or FAPI, as one of the APIs for PERFOROMIST's approved indications, other than PERFOROMIST, during the term of the co-promotion agreement. Notwithstanding the foregoing, if Critical Therapeutics signs a definitive agreement to be acquired by or merged with a third party that markets, manufactures, sells, details or promotes a product containing FAPI for sale in the United States, then, in lieu of the foregoing non-competition provision, Critical Therapeutics has agreed to specified restrictions on the activities of its sales representatives for a specified 180-day period.

If Critical Therapeutics signs a definitive agreement to be acquired by or merged with a third party that markets, manufactures, sells, details or promotes a product containing FAPI for sale in the United States, each party will have

the right to terminate the co-promotion agreement with three business days advance written



notice. Each party has the right to terminate the co-promotion agreement upon the occurrence of a material uncured breach by the other party.

### *MedImmune Collaboration*

In July 2003, Critical Therapeutics entered into an exclusive license and collaboration agreement with MedImmune to jointly develop products directed towards HMGB1. This agreement was amended in December 2005. Under the terms of the agreement, Critical Therapeutics granted MedImmune an exclusive worldwide license, under patent rights and know-how controlled by Critical Therapeutics, to make, use and sell products, including antibodies, that bind to, inhibit or inactivate HMGB1 and are used in the treatment or prevention, but not the diagnosis, of diseases, disorders and medical conditions.

Critical Therapeutics and MedImmune determine the extent of the collaboration on research and development matters each year upon the renewal of a rolling three-year research plan. Critical Therapeutics is currently working with MedImmune to evaluate the potential of a series of fully human monoclonal antibodies as agents for development as therapeutic antibodies to enable them to enter clinical development. Under the terms of the agreement, MedImmune has agreed to fund and expend efforts to research and develop at least one HMGB1-inhibiting product for two indications through specified clinical phases.

Under the collaboration, MedImmune has paid Critical Therapeutics initial fees of \$12.5 million. Critical Therapeutics may also receive research and development payments from MedImmune, including a minimum of \$4.0 million of research and development payments through the end of 2006, all of which had been paid by December 31, 2007. In addition, Critical Therapeutics may receive, subject to the terms and conditions of the agreement, other payments upon the achievement of research, development and commercialization milestones up to a maximum of \$124.0 million, after taking into account payments that Critical Therapeutics is obligated to make to The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute), or The Feinstein Institute, on milestone payments Critical Therapeutics receive from MedImmune. MedImmune also has agreed to pay royalties to Critical Therapeutics based upon net sales by MedImmune of licensed products resulting from the collaboration. MedImmune's obligation to pay Critical Therapeutics royalties continues on a product-by-product and country-by-country basis until the later of 10 years from the first commercial sale of a licensed product in each country and the expiration of the patent rights covering the product in that country. Critical Therapeutics is obligated to pay a portion of any milestone payments or royalties Critical Therapeutics receives from MedImmune to The Feinstein Institute, which initially licensed to Critical Therapeutics patent rights and know-how related to HMGB1. In connection with entering into the collaboration agreement, an affiliate of MedImmune purchased an aggregate of \$15.0 million of Critical Therapeutics' series B convertible preferred stock in October 2003 and March 2004, which converted into 2,857,142 shares of Critical Therapeutics common stock in June 2004 in connection with Critical Therapeutics' initial public offering.

In December 2005, MedImmune agreed that the collaboration demonstrated proof of concept in two preclinical disease models with human HMGB1 monoclonal antibodies. As a result, MedImmune made a \$1.25 million milestone payment to Critical Therapeutics. In December 2005, MedImmune agreed to fund an additional \$1.0 million of research work performed by Critical Therapeutics' full-time employees in 2006. In March 2007, MedImmune agreed to fund an additional \$125,000 of research work performed by Critical Therapeutics' full-time employees in 2007.

Critical Therapeutics has agreed to work exclusively with MedImmune in the research and development of HMGB1-inhibiting products. Under the terms of the agreement, MedImmune's license to commercialize HMGB1-inhibiting products generally excludes Critical Therapeutics from manufacturing, promoting or selling the licensed products. However, Critical Therapeutics has the option to co-promote in the United States the first product for the first indication approved in the United States, for which Critical Therapeutics must pay a portion of the

ongoing development costs and will receive a proportion of the profits in lieu of royalties that would otherwise be owed to Critical Therapeutics. MedImmune has the right to terminate Critical Therapeutics' co-promotion option in connection with a change of control of Critical Therapeutics.

MedImmune has the right to terminate the agreement at any time on six-months written notice. Each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. Under specified conditions, Critical Therapeutics or MedImmune may have certain payment or royalty obligations after the termination of the agreement.

### ***Beckman Coulter Collaboration***

In January 2005, Critical Therapeutics entered into a license agreement with Beckman Coulter relating to the development of diagnostic products for measuring HMGB1. Under the terms of the agreement, Critical Therapeutics granted to Beckman Coulter and its affiliates an exclusive worldwide license, under patent rights and know-how controlled by Critical Therapeutics relating to the use of HMGB1 and its antibodies in diagnostics, to evaluate, develop, make, use and sell a kit or assemblage of reagents for measuring HMGB1 that utilizes one or more monoclonal antibodies to HMGB1 developed by Critical Therapeutics or on its behalf.

In consideration for the license, Beckman Coulter paid Critical Therapeutics a product evaluation license fee of \$250,000. Beckman Coulter exercised its development option under the license agreement in December 2006 and paid Critical Therapeutics \$400,000 in January 2007. Under the agreement, Critical Therapeutics may also receive additional aggregate license fees of up to \$450,000 upon the achievement of the first commercial sale of a licensed product. Beckman Coulter also agreed to pay Critical Therapeutics royalties based on net sales of licensed products by Beckman Coulter and its affiliates. Beckman Coulter has the right to grant sublicenses under the license, subject to Critical Therapeutics written consent, which Critical Therapeutics has agreed not to unreasonably withhold. In addition, Beckman Coulter agreed to pay Critical Therapeutics a percentage of any license fees, milestone payments or royalties actually received by Beckman Coulter from its sublicensees.

Beckman Coulter has the right to terminate the license agreement at any time on 90-days written notice. Each party has the right to terminate the license agreement upon the occurrence of a material uncured breach by the other party.

### **Development**

As of June 30, 2008, Critical Therapeutics had three employees engaged in development and regulatory. During the first quarter of 2008 and the fiscal years ended December 31, 2007, 2006 and 2005, research and development expenses were \$5.4 million, \$21.7 million, \$26.9 million and \$30.0 million, respectively.

### **Sales and Marketing**

Critical Therapeutics has a respiratory sales force of approximately 29 representatives as of June 30, 2008, who are focused on promoting ZYFLO CR and PERFOROMIST to prescribing physicians within major markets across the United States. Under Critical Therapeutics co-promotion agreement with DEY, DEY has agreed to provide a minimum number of details per month for in the second position to office-based physicians and other health care professionals, including a minimum number of details delivered to respiratory specialists, such as allergists and pulmonologists. Critical Therapeutics has agreed to provide a minimum number of details per month for ZYFLO CR in the first position. In addition, under the co-promotion agreement with DEY for PERFOROMIST, Critical Therapeutics has agreed to provide a minimum number of primary detail equivalents per month for PERFOROMIST to a specified group of office-based physicians and other health care professionals.

Critical Therapeutics is focusing its sales and marketing efforts for ZYFLO CR on respiratory specialists who treat asthma, including allergists and pulmonologists, and primary care physicians who treat large numbers of asthma patients. Critical Therapeutics believes that within this targeted group there are approximately 100 to 200 national and regional scientific and clinical key opinion leaders who serve to influence the direction of the diagnosis and treatment

of asthma through their publications and presentations at scientific and clinical medical conferences. Critical Therapeutics also expects to focus its medical outreach efforts on local, clinically-based key opinion leaders.

Given the importance of the scientific and clinical key opinion leaders, Critical Therapeutics is directing its scientific message and support to help educate and inform key opinion leaders regarding the scientific rationale and clinical data that support its commercialization strategy. Critical Therapeutics has entered into consulting arrangements with a number of key opinion leaders who provide expert advice to it.

In June 2007, the NHLBI released an updated version of the Guidelines for the Diagnosis and Management of Asthma. In these guidelines, zileuton is specifically mentioned in steps three and four in the treatment spectrum as an alternative option in the treatment of asthma. This is the first time zileuton has been mentioned in these guidelines, and Critical Therapeutics believes this may provide additional scientific credibility to ZYFLO CR in the marketplace. In addition to the changes in the recommended treatment protocol for asthma, the updated guidelines continue to support the transition to the discussion of asthmatic patients in terms of their level of control rather than their severity level.

### **Manufacturing and Supply**

Critical Therapeutics has limited experience in manufacturing its products and product candidates. Critical Therapeutics currently outsources the manufacturing of ZYFLO CR and ZYFLO for commercial sale and the manufacturing of its product candidates for use in clinical trials to qualified third parties and intends to continue to rely on contract manufacturing from third parties to supply products for both clinical use and commercial sale.

In January 2008, Critical Therapeutics requested and received from the FDA a waiver from the requirement to provide six-months notice to cease manufacturing ZYFLO. In February 2008, Critical Therapeutics stopped the manufacture and supply of ZYFLO to the market. In March 2008, Critical Therapeutics began to experience supply chain issues with batches of ZYFLO CR that cannot be released into Critical Therapeutics commercial supply chain because they did not meet its product release specifications. In conjunction with Critical Therapeutics three third-party manufacturers for zileuton API, tablet cores and coating and release, Critical Therapeutics initiated an investigation to determine the cause of this issue, but the investigation is ongoing and is not yet complete. To date, the investigation has not identified a clear source of the issue. As of June 30, 2008, Critical Therapeutics recorded an inventory reserve with respect to seven additional batches of the tablet cores of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. 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. As of July 18, 2008, Critical Therapeutics does not have available any additional supplies of finished ZYFLO CR tablets to ship to its wholesale distributors though eight additional batches are currently in process and may be releasable once release specification testing is completed. 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, Critical Therapeutics estimates that wholesale distributors and retail pharmacies have a sufficient inventory of ZYFLO CR to continue to provide product to patients through the end of August 2008.

In April 2008, Critical Therapeutics began to reinstate manufacture of ZYFLO in order to have a supply of ZYFLO available to help manage the potential impact to patients given the supply chain issues being experienced for ZYFLO CR. In addition, Critical Therapeutics has received a number of requests from patients and physicians to bring ZYFLO back to the market. In July 2008, Critical Therapeutics notified the FDA of its intent to resume the manufacture, sale and marketing of ZYFLO. Critical Therapeutics expects to resume distribution of ZYFLO in August 2008.

Critical Therapeutics has established the following manufacturing arrangements for zileuton.

#### ***Shasun Pharma Solutions***

Critical Therapeutics originally contracted with Rhodia Pharma Solutions Ltd. for the commercial production of the zileuton API. On March 31, 2006, Rhodia SA, the parent company of Rhodia Pharma Solutions, sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhodia SA assigned Critical Therapeutics contract with Rhodia Pharma Solutions Ltd.

to Shasun. Under Critical Therapeutics' agreement with Shasun, as amended, Shasun has agreed to manufacture Critical Therapeutics' commercial supplies of API, subject to specified limitations, through the earlier of the date on which Critical Therapeutics has purchased a specified amount of the API for zileuton and December 31, 2010. The agreement will automatically extend for successive one-year periods after December 31, 2010, unless Shasun provides Critical Therapeutics with 18-months' prior written notice of cancellation. Critical Therapeutics has the right to terminate the agreement upon 12-months' prior written notice for any reason, provided that Critical Therapeutics may not cancel prior to the earlier of December 31, 2010 or the date on which it has purchased a specified amount of the API. Critical Therapeutics also has the right to terminate the agreement upon six-months' prior written notice if it terminates its plans to commercialize zileuton for all therapeutic indications. In addition, Critical Therapeutics has the right to terminate the agreement upon 30-days' prior written notice if any governmental agency takes any action, or raises any objection, that prevents Critical Therapeutics from importing, exporting, or selling zileuton products or the API. If Critical Therapeutics exercises its right to terminate the agreement prior to its scheduled expiration, Critical Therapeutics is obligated to reimburse Shasun for specified raw material and out-of-pocket costs. In addition, if Critical Therapeutics exercises its right to terminate the agreement due to termination of Critical Therapeutics' plans to commercialize zileuton for all therapeutic indications, then Critical Therapeutics is also obligated to pay Shasun for all API manufactured by Shasun through that date. Furthermore, each party has the right to immediately terminate the agreement for cause, including a material uncured default by the other party.

#### ***Jagotec***

Critical Therapeutics has contracted with Jagotec for the manufacture and supply of bulk, uncoated tablets of ZYFLO CR for Critical Therapeutics for commercial sale. Critical Therapeutics has agreed to purchase minimum quantities of ZYFLO CR during each 12-month period for the first five years following marketing approval of ZYFLO CR by the FDA. For the term of the contract, Critical Therapeutics has agreed to purchase specified amounts of its requirements for ZYFLO CR from Jagotec. The commercial manufacturing agreement has an initial term of five years beginning on May 22, 2007, and will automatically continue thereafter, unless Critical Therapeutics provides Jagotec with 24-months' prior written notice of termination or Jagotec provides Critical Therapeutics with 36-months' prior written notice of termination. In addition, Critical Therapeutics has the right to terminate the agreement upon 30-days' prior written notice in the event any governmental agency takes any action, or raises any objection, that prevents Critical Therapeutics from importing, exporting or selling ZYFLO CR. Critical Therapeutics also may terminate the agreement upon six-months' advance notice in the event that an AB-rated generic pharmaceutical product containing zileuton is introduced in the United States and Critical Therapeutics determines to permanently cease commercialization of ZYFLO CR. Likewise, Critical Therapeutics may terminate the agreement upon 12-months' advance notice if it intends to discontinue commercializing ZYFLO CR tablets. Furthermore, each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. In the event either party terminates the agreement, Critical Therapeutics agreed to purchase quantities of ZYFLO CR tablets that are subject to binding forecasts.

#### ***Patheon Pharmaceuticals***

Critical Therapeutics has contracted with Patheon to coat, conduct quality control and quality assurance and stability testing and package commercial supplies of ZYFLO CR. Under this agreement, Critical Therapeutics is responsible for supplying uncoated ZYFLO CR tablets to Patheon. Critical Therapeutics has agreed to purchase at least 50% of its requirements for such manufacturing services for ZYFLO CR for sale in the United States from Patheon each year during the term of this agreement. This agreement has an initial term of three years beginning May 9, 2007, and will automatically continue for successive one-year periods thereafter, unless Critical Therapeutics provides Patheon with 12-months' prior written notice of termination or Patheon provides Critical Therapeutics with 18-months' prior written notice of termination. In addition, Critical Therapeutics has the right to terminate this agreement upon 30-days' prior written notice in the event that any governmental agency takes any action, or raises any objection, that prevents

Critical Therapeutics from importing, exporting, purchasing or selling ZYFLO CR. Critical Therapeutics also has the right to terminate



this agreement upon 90-days prior written notice if an AB-rated generic product to ZYFLO CR is introduced in the United States. If Critical Therapeutics provides six-months advance notice that it intends to discontinue commercializing ZYFLO CR, Critical Therapeutics will not be required to purchase any additional quantities of ZYFLO CR finished tablets from Patheon, provided that Critical Therapeutics pays Patheon for a portion of specified fees and expenses associated with orders Critical Therapeutics previously placed. Patheon has the right to terminate this agreement if Critical Therapeutics assigns any of Critical Therapeutics' rights under the agreement to an assignee other than a purchaser or merger partner that, in Patheon's reasonable opinion, is not a credit worthy substitute for Critical Therapeutics, is a competitor of Patheon or is an entity with whom Patheon has had prior unsatisfactory business relations. Furthermore, each party has the right to terminate this agreement upon the occurrence of a material uncured breach by the other party. If this agreement expires or is terminated for any reason, Critical Therapeutics has agreed to take delivery of and pay for undelivered quantities of ZYFLO CR that it previously ordered, purchase, at cost, Patheon's inventory of ZYFLO CR maintained in contemplation of filling orders previously placed by Critical Therapeutics and pay the purchase price for components ordered by Patheon from suppliers in reliance on orders Critical Therapeutics previously placed.

Critical Therapeutics has contracted with Patheon for the manufacture of commercial supplies of ZYFLO immediate release tablets. Critical Therapeutics has agreed to purchase at least 50% of its commercial supplies of ZYFLO immediate-release tablets for sale in the United States from Patheon each year for the term of the agreement. The commercial manufacturing agreement has an initial term of three years beginning on September 15, 2005, and will automatically continue for successive one-year periods thereafter, unless Critical Therapeutics provides Patheon with 12-months prior written notice of termination or Patheon provides Critical Therapeutics with 18-months prior written notice of termination. In addition, Critical Therapeutics has the right to terminate the agreement upon 30-days prior written notice in the event any governmental agency takes any action, or raises any objection, that prevents it from importing, exporting, purchasing or selling ZYFLO. If Critical Therapeutics provides six-months advance notice that it intends to discontinue commercializing ZYFLO, Critical Therapeutics will not be required to purchase any additional quantities of ZYFLO immediate release tablets, provided that it must pay Patheon for a portion of specified fees and expenses associated with orders previously placed by Critical Therapeutics. Furthermore, each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. If the agreement expires or is terminated for any reason, Critical Therapeutics has agreed to take delivery of and pay for undelivered quantities of ZYFLO that it previously ordered, purchase, at cost, Patheon's inventory of ZYFLO maintained in contemplation of filling orders previously placed by Critical Therapeutics and pay the purchase price for components of the ZYFLO immediate release tablets ordered by Patheon from suppliers in reliance on orders previously placed by Critical Therapeutics.

### *CyDex*

Critical Therapeutics has entered into a license and supply agreement with CyDex, Inc., or CyDex, relating to Critical Therapeutics' clinical development and planned commercialization of zileuton injection. Under this agreement, CyDex granted to Critical Therapeutics a worldwide, exclusive license, under patent rights controlled by CyDex relating to CyDex's CAPTISO® drug enablement technology, for use with zileuton, under which Critical Therapeutics can develop, make, use and sell zileuton combined with or formulated using CAPTISOL in an injectable dosage form for ultimate use in humans. In addition, CyDex granted Critical Therapeutics a worldwide, non-exclusive license to utilize CyDex's toxicology and safety and other relevant scientific data, relating to CAPTISOL, to develop, make, use and sell in combination with zileuton. Under this agreement, Critical Therapeutics agreed that it and its affiliates and sublicensees will purchase CAPTISOL exclusively from CyDex, and CyDex has agreed to supply 100% of Critical Therapeutics and its affiliates' and sublicensees' requirements for CAPTISOL up to a specified amount per year during the term of the agreement.

In consideration for the licenses granted to Critical Therapeutics under the agreement, Critical Therapeutics paid CyDex an initial license fee of \$50,000 and agreed to make aggregate milestone payments of up to \$2.9 million upon the achievement of specified development, regulatory and commercialization milestones for

the combined product. In addition, Critical Therapeutics agreed to pay royalties to CyDex based on net sales of the combined product by Critical Therapeutics and its affiliates and licensees. Critical Therapeutics' obligation to pay royalties expires, with respect to each country in which the combined product is commercialized, upon the later of the expiration of the last relevant patent that claims CAPTISOL in such country or ten years from the first commercial sale of the combined product in such country.

The term of the agreement expires upon the expiration of Critical Therapeutics' obligation to pay royalties. CyDex has the right to terminate the agreement upon the occurrence of an uncured breach by Critical Therapeutics. Critical Therapeutics has the right to terminate the agreement at any time upon 75-days' prior written notice.

### ***Other***

Critical Therapeutics expects to need to enter into manufacturing arrangements with third parties for the manufacture of Critical Therapeutics' other product candidates for clinical use. For example, Critical Therapeutics will need to enter into arrangements for the manufacture of product candidates for clinical trials in its alpha-7 program. Under Critical Therapeutics' collaboration agreement with MedImmune, MedImmune would be responsible for manufacturing any biologic products that result from the HMGB1 program.

### **Distribution Network**

Critical Therapeutics currently relies on third parties to distribute ZYFLO CR and ZYFLO to pharmacies. Critical Therapeutics has contracted with ICS, a third-party logistics company, to warehouse ZYFLO CR and ZYFLO and distribute it to three primary wholesalers, AmerisourceBergen Corporation, Cardinal Health and McKesson Corporation, and a number of smaller wholesalers. The wholesalers, in turn, distribute it to chain and independent pharmacies. ICS is Critical Therapeutics' exclusive supplier of commercial distribution logistics services.

Critical Therapeutics relies on Phoenix to distribute samples of ZYFLO CR and ZYFLO to Critical Therapeutics' sales representatives, who in turn distribute samples to physicians and other prescribers who are authorized under state law to receive and dispense samples. Critical Therapeutics relies on RxHope, Inc. to distribute samples ZYFLO CR to physicians and other prescribers who are authorized under state law to receive and dispense prescription drugs.

This distribution network requires significant coordination with Critical Therapeutics' supply chain, sales and marketing and finance organizations. Critical Therapeutics does not have its own warehouse or distribution capabilities. Critical Therapeutics does not intend to establish these functions on its own in the foreseeable future.

### **License and Royalty Agreements**

Critical Therapeutics has entered into a number of license agreements under which it has licensed intellectual property and other rights needed to develop its products or under which Critical Therapeutics has licensed intellectual property and other rights to third parties, including the license agreements summarized below.

### ***Abbott***

In December 2003, Critical Therapeutics acquired an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell controlled-release and injectable formulations of zileuton for all clinical indications, except for the treatment of children under age seven and use in cardiovascular and vascular devices. This license included an exclusive sublicense of Abbott's rights in proprietary controlled-release technology originally licensed to Abbott by Jagotec. In consideration for the license, Critical Therapeutics paid Abbott an initial \$1.5 million license fee and agreed to make aggregate milestone payments of up to \$13.0 million to Abbott upon the

achievement of various development and commercialization milestones, including the completion of the technology transfer from Abbott to Critical Therapeutics, filing and approval of a product in the United States and specified minimum net sales of licensed

products. In addition, Critical Therapeutics agreed to pay royalties to Abbott based on net sales of licensed products by Critical Therapeutics, its affiliates and sublicensees. Critical Therapeutics' obligation to pay royalties continues on a country-by-country basis for a period of ten years from the first commercial sale of a licensed product in each country. Upon the expiration of Critical Therapeutics' obligation to pay royalties for licensed products in a given country, the license will become perpetual, irrevocable and fully paid up with respect to licensed products in that country. If Critical Therapeutics decides to sublicense rights under the license, Critical Therapeutics must first enter into good faith negotiations with Abbott for the commercialization rights to the licensed product. Abbott waived its right of first negotiation with respect to Critical Therapeutics' co-promotion arrangement with DEY for ZYFLO CR. Each party has the right to terminate the license upon the occurrence of a material uncured breach by the other party. Critical Therapeutics also has the right to terminate the license at any time upon 60-days' notice to Abbott and payment of a termination fee. Through December 31, 2007, Critical Therapeutics has paid milestone and license payments totaling \$6.5 million to Abbott under this agreement. In addition, after the FDA approved the NDA for ZYFLO CR in May 2007, Critical Therapeutics accrued \$2.8 million in milestone payments it owes to Abbott on the first and second anniversary of the approval of the ZYFLO CR NDA.

In March 2004, Critical Therapeutics acquired from Abbott the U.S. trademark ZYFLO® and an exclusive worldwide license, under patent rights and know-how controlled by Abbott, to develop, make, use and sell the immediate-release formulation of zileuton for all clinical indications. In consideration for the license and the trademark, Critical Therapeutics paid Abbott an initial fee of \$500,000 and a milestone payment of \$750,000 upon approval of the sNDA, which Critical Therapeutics paid in October 2005, and Critical Therapeutics agreed to pay royalties based upon net sales of licensed products by Critical Therapeutics, its affiliates and sublicensees. Critical Therapeutics' obligation to pay royalties continues on a country-by-country basis for a period of ten years from the first commercial sale of a licensed product in each country. Upon the expiration of Critical Therapeutics' obligation to pay royalties in a given country, the license will become perpetual, irrevocable and fully paid up with respect to licensed products in that country. Each party has the right to terminate the license upon the occurrence of a material uncured breach by the other party.

### ***Baxter***

In June 2004, Critical Therapeutics entered into an agreement with Baxter Healthcare Corporation to conduct feasibility studies to analyze the various properties of zileuton and determine the most suitable technologies for the development of an injectable formulation of zileuton. In the event that Critical Therapeutics chooses to pursue the commercialization of a specified injectable formulation developed by Baxter that is based on the formulation technology of a third party, Baxter granted Critical Therapeutics an exclusive, worldwide, non-revocable license to the formulation intellectual property in return for Critical Therapeutics' agreement to pay Baxter royalties based on net sales of that formulation. However, Critical Therapeutics would need to finalize the license agreement to document such license based on the agreed financial terms, which Critical Therapeutics may not be able to negotiate on favorable terms, if at all. It is also possible that Critical Therapeutics may instead determine to pursue the commercialization of an injectable formulation developed by Baxter based on its own proprietary formulation technology. If Critical Therapeutics determines to do so, Critical Therapeutics would need to license from Baxter rights to that injectable formulation. In that case, Critical Therapeutics may not be able to negotiate a license agreement on favorable terms, if at all. Furthermore, although Baxter has filed two U.S. patent applications, one for the specified injectable formulation developed by Baxter based on the formulation technology of a third party and another for an injectable formulation developed by Baxter based on its own proprietary formulation technology, neither of these patent applications may result in issued patents.

### ***The Feinstein Institute***

In July 2001, Critical Therapeutics acquired from The Feinstein Institute an exclusive worldwide license, under patent rights and know-how controlled by The Feinstein Institute relating to HMGB1, to make, use and sell products covered by the licensed patent rights and know-how. The Feinstein Institute retained the right to make and use the licensed products in its own laboratories solely for non-commercial, scientific purposes and

non-commercial research. In consideration for the license, Critical Therapeutics paid an initial license fee of \$100,000. Critical Therapeutics also agreed to make milestone payments to The Feinstein Institute of up to \$275,000 for the first product covered by the licensed patent rights and an additional \$100,000 for each additional distinguishable product covered by the licensed patent rights, up to \$137,500 for the first product covered by the licensed know-how and not the licensed patent rights and an additional \$50,000 for each additional distinguishable product covered by the licensed know-how and not the licensed patent rights, in each case upon the achievement of specified development and regulatory milestones for the applicable licensed product. In addition, Critical Therapeutics agreed to pay The Feinstein Institute royalties based on net sales of licensed products by Critical Therapeutics and its affiliates until the later of ten years from the first commercial sale of each licensed product in a given country and the expiration of the patent rights covering the licensed product in that country. Critical Therapeutics agreed to pay minimum annual royalties to The Feinstein Institute beginning in July 2007 regardless of whether Critical Therapeutics sells any licensed products. Critical Therapeutics paid The Feinstein Institute \$15,000 for minimum royalties in 2007. Critical Therapeutics also agreed to pay The Feinstein Institute fees if Critical Therapeutics sublicenses its rights under the licensed patent rights and know-how. At December 31, 2007, Critical Therapeutics accrued \$13,000 owed to The Feinstein Institute in accordance with this agreement. Each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party.

Critical Therapeutics also has entered into two sponsored research and license agreements with The Feinstein Institute. In July 2001, Critical Therapeutics entered into a sponsored research and license agreement with The Feinstein Institute under which, as amended, Critical Therapeutics paid The Feinstein Institute \$200,000 annually until June 2006 to sponsor research activities at The Feinstein Institute to identify inhibitors and antagonists of HMGB1 and related proteins, including antibodies. In January 2003, Critical Therapeutics entered into a sponsored research and license agreement with The Feinstein Institute under which, as amended, Critical Therapeutics agreed to pay The Feinstein Institute to sponsor research activities at The Feinstein Institute in the field of cholinergic anti-inflammatory technology. Critical Therapeutics paid the Feinstein Institute \$200,000 annually until January 2006 and \$150,000 in 2006 and \$120,000 in 2007 for this sponsored research. Any future research terms under either of these agreements are subject to agreement between The Feinstein Institute and Critical Therapeutics. Under the terms of these agreements, Critical Therapeutics acquired an exclusive worldwide license to make, use and sell products covered by the patent rights and know-how arising from the sponsored research. The Feinstein Institute retained the right under each of these agreements to make and use the licensed products in its own laboratories solely for non-commercial, scientific purposes and non-commercial research. Each party has the right to terminate each agreement upon the occurrence of a material uncured breach of that agreement by the other party.

In connection with the July 2001 sponsored research and license agreement, Critical Therapeutics issued The Feinstein Institute 27,259 shares of Critical Therapeutics common stock and agreed to make milestone payments to The Feinstein Institute of \$200,000 for the first product covered by the licensed patent rights, and an additional \$100,000 for each additional distinguishable product covered by the licensed patent rights, \$100,000 for the first product covered by the licensed know-how and not the licensed patent rights and an additional \$50,000 for each additional distinguishable product covered by the licensed know-how and not the licensed patent rights, in each case upon the achievement of specified development and regulatory approval milestones with respect to the applicable licensed product. In connection with the January 2003 sponsored research and license agreement, Critical Therapeutics paid The Feinstein Institute an initial license fee of \$175,000 and agreed to pay additional amounts in connection with the filing of any U.S. patent application or issuance of a U.S. patent relating to the field of cholinergic anti-inflammatory technology. Critical Therapeutics also agreed to make aggregate milestone payments to The Feinstein Institute of up to \$1.5 million in both cash and shares of Critical Therapeutics common stock upon the achievement of specified development and regulatory approval milestones with respect to any licensed product. In addition, under each of these agreements, Critical Therapeutics agreed to pay The Feinstein Institute royalties based on net sales of a licensed product by Critical Therapeutics and its affiliates until the later of ten years from the first commercial sale of licensed products in a given country and the expiration of the patent rights covering the licensed

product in that country. Under the January 2003 sponsored research and license agreement, Critical Therapeutics agreed to pay minimum annual royalties to The Feinstein Institute beginning in the first



year after termination of research activities regardless of whether Critical Therapeutics sells any licensed products. At December 31, 2007, Critical Therapeutics owed \$30,000 to The Feinstein Institute in accordance with the January 2003 agreement.

Critical Therapeutics also agreed to pay The Feinstein Institute certain fees if Critical Therapeutics sublicenses its rights under the licensed patent rights and know-how under either agreement. In connection with Critical Therapeutics sublicenses to MedImmune and Beckman Coulter of Critical Therapeutics' rights with respect to HMGB1, Critical Therapeutics paid The Feinstein Institute \$2.5 million and issued to The Feinstein Institute 66,666 shares of Critical Therapeutics' common stock. In connection with Critical Therapeutics' January 2007 sublicense to IMI of Critical Therapeutics' rights with respect to vagus nerve stimulation, Critical Therapeutics has paid The Feinstein Institute \$100,000 and arranged for the issuance by IMI to The Feinstein Institute of 100,000 shares of junior preferred stock of IMI.

### *Jagotec AG*

In December 2003, Critical Therapeutics entered into an agreement with Jagotec under which Jagotec consented to Abbott's sublicense to Critical Therapeutics of rights to make, use and sell ZYFLO CR covered by Jagotec's patent rights and know-how. Under the terms of the agreement, Jagotec also agreed to manufacture ZYFLO CR for clinical trials, regulatory review and, upon FDA approval and subject to negotiating a manufacturing agreement, commercial sale. In consideration for Jagotec's prior work associated with the licensed patent rights and know-how, Critical Therapeutics paid Jagotec an upfront fee of \$750,000. Critical Therapeutics also agreed to make aggregate milestone payments to Jagotec of up to \$6.6 million upon the achievement of various development and commercialization milestones. Through December 31, 2007, Critical Therapeutics has made milestone payments totaling \$3.0 million to Jagotec under this agreement. In addition, after the FDA approved the NDA for ZYFLO CR in May 2007, Critical Therapeutics accrued an additional \$699,000 in milestone payments it owes to Jagotec on the first and second anniversary of the approval of the NDA for ZYFLO CR. In addition, Critical Therapeutics agreed to pay royalties to Jagotec based upon net sales of the product by Critical Therapeutics and its affiliates. Critical Therapeutics also agreed to pay royalties to Jagotec under the license agreement between Jagotec and Abbott based upon net sales of the product by Critical Therapeutics and its affiliates. In addition, Critical Therapeutics agreed to pay Jagotec fees if Critical Therapeutics sublicenses its rights under the licensed patent rights and know-how. In 2005, Jagotec agreed to allow Critical Therapeutics to sublicense its rights to Patheon to permit Patheon to manufacture a portion of Critical Therapeutics' annual requirements for ZYFLO CR tablets. Each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party.

### *Innovative Metabolics*

In January 2007, Critical Therapeutics entered into an exclusive license agreement with IMI under which Critical Therapeutics granted to IMI an exclusive worldwide license under patent rights and know-how controlled by Critical Therapeutics relating to the stimulation of the vagus nerve to make, use and sell products and methods covered by the licensed patent rights and know-how in the licensed field. The licensed field includes mechanical and electrical stimulation of the vagus nerve and excludes pharmacological modulation of a cholinergic receptor, including the alpha-7 receptor. In consideration for the license, IMI paid Critical Therapeutics an initial license fee of \$400,000 in cash after taking into account payments that Critical Therapeutics is obligated to make to The Feinstein Institute. In addition, in connection with IMI's first financing, IMI issued to Critical Therapeutics a number of shares of junior preferred stock of IMI equal to the number of shares of preferred stock that could be purchased for \$400,000 in such financing after taking into account payments that Critical Therapeutics is obligated to make to The Feinstein Institute. The junior preferred stock issued to Critical Therapeutics had a liquidation preference subordinate to the preferred stock issued in such financing. In March 2008, Critical Therapeutics sold these 400,000 shares of junior preferred stock to two investors, which had participated in IMI's first financing, for an aggregate purchase price of \$400,000.

The purchase price is subject to adjustment if these investors sell or receive consideration for these shares of junior preferred stock pursuant to an acquisition of IMI prior to February 1, 2009 at a price per share greater than they paid Critical Therapeutics.

Under this license agreement, IMI also agreed to:

make a one-time milestone payment to Critical Therapeutics of \$1.0 million upon the achievement of all regulatory approvals from the FDA or any foreign counterpart agency required for the marketing and sale in the applicable country of any product or method covered by the licensed patent rights;

pay Critical Therapeutics royalties based on net sales of licensed products and methods by IMI and its affiliates until the expiration of the patent rights covering the licensed product or method in the country of actual or intended use; and

pay Critical Therapeutics a percentage of any royalties, fees and payments actually received from third parties, with limited exceptions, in connection with sublicenses by IMI of its rights under the licensed patent rights and know-how.

The patent rights and know-how licensed by Critical Therapeutics to IMI include patent rights and know-how arising from research conducted by The Feinstein Institute under the sponsored research and license agreement, as amended, that Critical Therapeutics entered into with The Feinstein Institute in January 2003.

Under this license agreement, IMI agreed to be responsible for specified obligations Critical Therapeutics owes to The Feinstein Institute pursuant to Critical Therapeutics' sponsored research and license agreement. IMI agreed to financially support sponsored research under the sponsored research and license agreement to the extent that the sponsored research is in the licensed field under the IMI license agreement. IMI also agreed to reimburse Critical Therapeutics for a portion of:

amounts payable to The Feinstein Institute in connection with the filing of any U.S. patent application or issuance of a U.S. patent relating to the field of cholinergic anti-inflammatory technology; and

minimum annual royalties payable to The Feinstein Institute beginning in the first year after termination of research activities under the sponsored research agreement.

Each party has the right to terminate the license agreement upon the occurrence of a material uncured default by the other party. IMI has the right to terminate the IMI license agreement at any time on 90-days' prior written notice to Critical Therapeutics.

Two of Critical Therapeutics' co-founders, Kevin J. Tracey, M.D. and H. Shaw Warren, M.D., are founders of IMI. Dr. Warren served as a member of the Critical Therapeutics Board of Directors until October 2006. Dr. Tracey is a member of the medical staff at The Feinstein Institute. In addition, Critical Therapeutics is a party to a consulting agreement with Dr. Tracey that terminates on December 31, 2009. Furthermore, Critical Therapeutics was previously a party to a consulting agreement with Dr. Warren that terminated on January 1, 2008. Under Critical Therapeutics' consulting agreement with Dr. Tracey, Critical Therapeutics agreed to pay certain royalties to Dr. Tracey in connection with selling or sublicensing certain licensed alpha-7 products as defined in the agreement.

### **Proprietary Rights**

Critical Therapeutics' success depends in part on its ability to obtain and maintain proprietary protection for its product candidates, technology and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing Critical Therapeutics' proprietary rights. Critical Therapeutics' policy is to seek to protect its proprietary position by, among other methods, filing U.S. and foreign patent applications related to its proprietary technology, inventions and improvements that are important to the development of its business and obtaining, where

possible, assignment of invention agreements from employees and consultants. Critical Therapeutics also relies on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain its proprietary position.

As of June 30, 2008, Critical Therapeutics owns or exclusively licenses for one or more indications or formulations a total of 16 issued U.S. patents, 50 issued foreign patents, 23 pending U.S. patent applications and 64 pending foreign patent applications consisting of:

	U.S.		Foreign		Program Total
	Issued	Pending	Issued	Pending	
Zileuton	2	1	18	2	23
HMGB1	10	13	22	35	80
Alpha-7	4	9	10	27	50
<b>Total</b>	16	23	50	64	153

The U.S. patent covering the composition of matter of zileuton that Critical Therapeutics licensed from Abbott expires in December 2010. The patent for ZYFLO CR will expire in June 2012 and relates only to the controlled-release technology used to control the release of zileuton. The U.S. issued patents that Critical Therapeutics owns or exclusively licenses covering Critical Therapeutics' product candidates other than zileuton expire on various dates between 2019 and 2021.

The patent position of pharmaceutical or biotechnology companies, including Critical Therapeutics, is generally uncertain and involves complex legal and factual considerations. Critical Therapeutics' success depends, in part, on its ability to protect proprietary products, methods and technologies that it develops under the patent and other intellectual property laws of the United States and other countries, so that Critical Therapeutics can prevent others from using its inventions and proprietary information. If any parties should successfully claim that Critical Therapeutics' proprietary products, methods and technologies infringe upon their intellectual property rights, Critical Therapeutics might be forced to pay damages, and a court could require it to stop the infringing activity. Critical Therapeutics does not know if its pending patent applications will result in issued patents. Critical Therapeutics' issued patents and those that may issue in the future, or those licensed to Critical Therapeutics, may be challenged, invalidated or circumvented, which could limit Critical Therapeutics' ability to stop competitors from marketing related products or the length of term of patent protection that it may have for its products. In addition, the rights granted under any issued patents may not provide Critical Therapeutics with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, Critical Therapeutics' competitors may independently develop similar technologies or duplicate any technology developed by it. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of Critical Therapeutics' product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

#### ***Trademarks, Trade Secrets and Other Proprietary Information***

Critical Therapeutics has registered the Critical Therapeutics name and logo in both the United States and the European Community. Critical Therapeutics has registered ZYFLO CR and CT2 in the United States. Critical Therapeutics has also filed trademark applications to register CRTX in the United States. In March 2004, Critical Therapeutics acquired the U.S. trademark for ZYFLO from Abbott.

In addition, Critical Therapeutics depends upon trade secrets, know-how and continuing technological advances to develop and maintain Critical Therapeutics' competitive position. To maintain the confidentiality of trade secrets and proprietary information, it is Critical Therapeutics' general practice to enter into confidentiality agreements with its

employees, consultants, strategic partners, outside scientific collaborators and sponsored researchers and other advisors. These agreements are designed to protect Critical Therapeutics' proprietary information. These agreements are designed to deter, but may not prevent, unauthorized disclosure of Critical Therapeutics' trade secrets, and any such unauthorized disclosure would have a material adverse effect on Critical Therapeutics' business, for which monetary damages from the party making such unauthorized disclosure may not be adequate to compensate Critical Therapeutics.

## Regulatory Matters

The research, testing, manufacture and marketing of drug and biologic products are extensively regulated in the United States and abroad. In the United States, drugs and biologics are subject to rigorous regulation by the FDA. The federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, packaging, labeling, advertising and promotion, sampling and distribution of pharmaceutical and biologic products. The failure to comply with the applicable regulatory requirements may subject Critical Therapeutics to a variety of administrative or judicially imposed sanctions, including the FDA's refusal to file new applications or to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

The steps ordinarily required before a new pharmaceutical or biologic product may be marketed in the United States include preclinical laboratory tests, animal tests and formulation studies, the submission to the FDA of an IND, which must become effective prior to commencement of human clinical testing, and adequate and well-controlled clinical trials to establish that the product is safe and effective for the indication for which FDA approval is sought. Satisfaction of FDA approval requirements typically takes several years and the actual time taken may vary substantially depending upon the complexity of the product, disease or clinical trials required. Government regulation may impose costly procedures on Critical Therapeutics' activities, and may delay or prevent marketing of potential products for a considerable period of time or prevent such marketing entirely. Success in early stage clinical trials does not necessarily assure success in later stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in marketing or sales restrictions on the product or even complete withdrawal of the product from the market.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of compounds for testing must comply with federal regulations and requirements. The results of preclinical testing are submitted to the FDA as part of an IND during the IND stage of development and as part of the NDA.

An IND must become effective prior to the commencement of clinical testing of a drug or biologic in humans. An IND will automatically become effective 30 days after receipt by the FDA if the FDA has not commented on or questioned the application during this 30-day waiting period. If the FDA has comments or questions, these may need to be resolved to the satisfaction of the FDA prior to commencement of clinical trials. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. The IND process can result in substantial delay and expense.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations and requirements, under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the safety and effectiveness criteria to be evaluated. Each protocol for an unapproved drug involving testing human subjects in the United States must be submitted to the FDA as part of the IND. The trial protocol and informed consent information for subjects in clinical trials must be submitted to institutional review boards for approval.

Clinical trials to support new drug or biologic product applications for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the product candidate into healthy human subjects or patients, the product is tested to assess metabolism, pharmacokinetics, safety, including side effects associated with increasing doses, and, at times, pharmacological actions. Phase II usually involves trials in a limited patient population, to determine dosage tolerance and optimum dosage, identify possible adverse effects and safety risks, and provide preliminary support for the efficacy of the product in the indication being studied.



If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to evaluate further clinical efficacy and to test further for safety within an expanded patient population, typically at geographically dispersed clinical trial sites. Phase I, Phase II or Phase III testing of any product candidates may not be completed successfully within any specified time period, if at all. Furthermore, the FDA, an institutional review board or Critical Therapeutics may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

After successful completion of the required clinical testing for a drug, generally an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all clinical and preclinical safety testing and a compilation of the data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of NDAs are additionally subject to substantial application user fees, currently exceeding \$1,100,000, the fee for submission of supplemental applications exceeds \$580,000 and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently exceeding \$65,000 per product and up to \$392,000 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The review process is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA normally also will conduct a pre-approval inspection to ensure the manufacturing facility, methods and controls are adequate to preserve the drug's identity, strength, quality, purity and stability, and are in compliance with regulations governing current good manufacturing practices. In addition, the FDA usually conducts audits of the clinical trials for new drug applications and efficacy supplements to ensure that the data submitted reflects the data generated by the clinical sites.

If the FDA's evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue an approval letter, or, in some cases, an approvable letter followed by an approval letter. An approvable letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require post-approval trials and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions and restricted distribution, which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Supplemental applications must be filed for many post-approval changes, including changes in manufacturing facilities.

Some of Critical Therapeutics' products may be regulated as biologics under the Public Health Service Act. Biologics must have a biologics license application, or BLA, approved prior to commercialization. Like NDAs, BLAs are subject to user fees. To obtain BLA approval, an applicant must provide preclinical and clinical evidence and other information to demonstrate that the biologic product is safe, pure and potent and that the facilities in which it is manufactured processed, packed or held meet standards, including good manufacturing practices and any additional standards in the license designed to ensure its continued safety, purity and potency. Biologics establishments are subject to preapproval inspections. The review process for BLAs is time consuming and uncertain, and BLA approval

may be conditioned on post-approval testing and surveillance. Once granted, BLA approvals may be suspended or revoked under certain circumstances, such as if the product fails to conform to the standards established in the license.

Once the NDA or BLA is approved, a product will be subject to certain post-approval requirements, including requirements for adverse event reporting and submission of periodic reports. In addition, the FDA strictly regulates the promotional claims that may be made about prescription drug products and biologics. In particular, the FDA requires substantiation of any claims of superiority of one product over another, including that such claims be proven by adequate and well-controlled head-to-head clinical trials. To the extent that market acceptance of Critical Therapeutics products may depend on their superiority over existing therapies, any restriction on Critical Therapeutics ability to advertise or otherwise promote claims of superiority, or requirements to conduct additional expensive clinical trials to provide proof of such claims, could negatively affect the sales of Critical Therapeutics products or Critical Therapeutics costs.

Critical Therapeutics must also notify the FDA of any change in an approved product beyond variations already allowed in the approval. Certain changes to the product, its labeling or its manufacturing require prior FDA approval, including conduct of further clinical investigations to support the change. Major changes in manufacturing site require submission of an sNDA and approval by the FDA prior to distribution of the product using the change. Such supplements, referred to as Prior Approval Supplements, must contain information validating the effects of the change. An applicant may ask the FDA to expedite its review of such a supplement for public health reasons, such as a drug shortage. Approvals of labeling or manufacturing changes may be expensive and time-consuming and, if not approved, the product will not be allowed to be marketed as modified.

If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA and issue a not approvable letter. The not approvable letter outlines the deficiencies in the submission and often requires additional testing or information in order for the FDA to reconsider the application. Even after submitting this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of an NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

Once an NDA is approved, the product covered thereby becomes a listed drug that can, in turn, be cited by potential competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active pharmaceutical ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. There is no requirement, other than the requirement for bioequivalence testing, for an ANDA applicant to conduct or submit results of preclinical or clinical tests to prove the safety or efficacy of its drug product. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, are listed as such by the FDA, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active pharmaceutical ingredients but is approved in a new dosage, dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor. During such three-year exclusivity period, the FDA cannot grant effective approval of an ANDA to commercially distribute a generic version of the drug based on that listed drug. However, the FDA can approve generic equivalents of that listed drug based on other listed drugs, such as a generic that is the same in every way but its indication for use, and thus the value of such exclusivity may be undermined. Federal law also provides a period of five years following approval of a drug containing no previously approved active pharmaceutical ingredients. During such five-year exclusivity period, ANDAs for generic versions of those drugs cannot be submitted unless the submission accompanies a challenge to a listed patent, in which case the submission may be made four years following the original product approval. Additionally, in the event that the sponsor of the listed drug has properly informed the FDA of patents covering its listed drug, applicants submitting an ANDA referencing that drug are required to make one of four certifications, including certifying that it believes one or more listed patents are invalid or not infringed. If an applicant certifies invalidity or non-infringement, it is required to provide notice of its

filing to the NDA sponsor and the patent holder. If the patent holder then initiates a suit for patent infringement against the ANDA sponsor within 45 days of receipt of the notice, the FDA cannot grant effective approval of the ANDA until either 30 months has passed or there has been a court decision holding that the patents in

question are invalid or not infringed. If the NDA holder and patent owners do not begin an infringement action within 45 days, the ANDA applicant may bring a declaratory judgment action to determine patent issues prior to marketing. If the ANDA applicant certifies that it does not intend to market its generic product before some or all listed patents on the listed drug expire, then FDA cannot grant effective approval of the ANDA until those patents expire. If more than one applicant files a substantially complete ANDA on the same day for a previously unchallenged drug, each such first applicant will be entitled to share the 180-day exclusivity period, but there will only be one such period, beginning on the date of first marketing by any of the first applicants. The first ANDA submitting substantially complete applications certifying that listed patents for a particular product are invalid or not infringed may qualify for a period of 180 days after the first marketing of the generic product, during which subsequently submitted ANDAs cannot be granted effective approval.

Violation of any FDA requirements could result in enforcement actions, such as withdrawal of approval, product recalls, product seizures, injunctions, total or partial suspension of production or distribution, fines, consent decrees, civil penalties and criminal prosecutions, which could have a material adverse effect on Critical Therapeutics business.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the development, approval, manufacturing and marketing of drug products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect Critical Therapeutics business and its products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

### ***Foreign Regulation***

Approval of a product by comparable regulatory authorities may be necessary in foreign countries prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. The approval procedure varies among countries and can involve requirements for additional testing. The time required may differ from that required for FDA approval. Although there are some procedures for unified filings for some European countries, such as the sponsorship of the country which first granted marketing approval, in general each country has its own procedures and requirements, many of which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from foreign regulatory authorities after the relevant applications are filed.

Under European Union regulatory systems, marketing authorization applications may be submitted at a centralized, a decentralized or a national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all European Union member states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. Critical Therapeutics will choose the appropriate route of European regulatory filing to accomplish the most rapid regulatory approvals. However, Critical Therapeutics chosen regulatory strategy may not secure regulatory approvals on a timely basis or at all.

### ***Hazardous Materials***

Critical Therapeutics previous research and development processes involved the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. Critical Therapeutics is subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. Critical Therapeutics does not expect the cost of complying with these laws and regulations to be material.

**Competition**

The pharmaceutical and biotechnology industries in which Critical Therapeutics operate are characterized by rapidly advancing technologies and intense competition. Critical Therapeutics competitors include

pharmaceutical companies, biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. All of these competitors currently engage in or may engage in the future in the development, manufacture and commercialization of new pharmaceuticals, some of which may compete with Critical Therapeutics' present or future products and product candidates. Many of Critical Therapeutics' competitors have greater development, financial, manufacturing, marketing and sales experience and resources than Critical Therapeutics does, and they may develop new products or technologies that will render Critical Therapeutics' products or technologies obsolete or noncompetitive. Critical Therapeutics cannot assure you that Critical Therapeutics' products will compete successfully with these newly emerging technologies. In some cases, competitors will have greater name recognition and may offer discounts as a competitive tactic.

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

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

Many therapies for COPD are already well established in the respiratory marketplace, including GlaxoSmithKline's Advair® and Serevent® and Spiriva®, a once-daily muscarinic antagonist from Boehringer 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. is conducting clinical trials of an intravenous formulation of its product Singulair®.

If Critical Therapeutics' therapeutic programs directed toward the body's inflammatory response result in commercial products, such products will compete predominantly with therapies that have been approved for diseases such as rheumatoid arthritis, like Amgen, Inc.'s Enbrel®, Johnson & Johnson's Remicade®, Bristol-Myers Squibb Company's Orencia®, Abbott Laboratories' Humira® and Rituxan® marketed by Biogen Idec Inc. and Genentech, Inc., and diseases such as sepsis, like Eli Lilly and Company's Xigris®. While non-steroidal, anti-inflammatory drugs like ibuprofen are often used for the treatment of rheumatoid arthritis and offer efficacy in reducing pain and inflammation, Critical Therapeutics believes that Critical Therapeutics' cytokine-based therapeutic programs will compete predominantly with the anti-TNF alpha therapies that have been approved for diseases such as rheumatoid arthritis, like Enbrel® and Remicade®. Xigris®, a product developed by Eli Lilly for sepsis, has received regulatory approval for severe sepsis patients. Other than a wide range of anti-infective drugs, Xigris is one of the only drugs approved by the FDA for the treatment of sepsis. Other companies are developing therapies directed towards cytokines. Critical Therapeutics does not know whether any or all of these products under development will ever reach the market and if they do, whether they will do so before or after Critical Therapeutics' products are approved.

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

significantly greater financial, technical and human resources than Critical Therapeutics has and may be better equipped to discover, develop, manufacture and commercialize products;



more extensive experience than Critical Therapeutics has in conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;

competing products that have already received regulatory approval or are in late-stage development; and

collaborative arrangements in Critical Therapeutics target markets with leading companies and research institutions.

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

### **Properties**

Critical Therapeutics subleases approximately 11,298 square feet of office space in Lexington, Massachusetts. The sublease expires on February 28, 2009, and Critical Therapeutics has an option to extend the term of the sublease for an additional six months. Critical Therapeutics believes its facilities are sufficient to meet its needs for the foreseeable future.

### **Employees**

As of June 30, 2008, Critical Therapeutics had 49 full-time employees, 34 of whom were engaged in marketing and sales, three of whom were engaged in development and regulatory affairs, and 12 of whom were engaged in management, administration and finance. None of Critical Therapeutics employees are represented by a labor union or covered by a collective bargaining agreement. Critical Therapeutics has not experienced any work stoppages. Critical Therapeutics believes that relations with its employees are good.

### **Access to SEC Filings**

Critical Therapeutics files reports, proxy statements and other information with the SEC as required by the Exchange Act. You can find, copy and inspect information Critical Therapeutics files at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can call the SEC at 1-800-SEC-0330 for further information about the public reference room. You can review Critical Therapeutics electronically filed reports, proxy and information statements on the SEC's web site at <http://www.sec.gov> or on Critical Therapeutics web site at <http://www.crtx.com>.

## CORNERSTONE S BUSINESS

### Overview

Cornerstone is a specialty pharmaceutical company focused on acquiring, developing and commercializing prescription products for the respiratory market. Cornerstone currently promotes four marketed products in the United States to respiratory-focused physicians and key retail pharmacies with its 50 person specialty sales force. Cornerstone's commercial strategy is to acquire non-promoted or underperforming branded pharmaceutical products and then maximize their potential value by promoting the products using its sales and marketing capabilities and applying various product life cycle management techniques. Cornerstone's product development pipeline consists of three line extensions of one of its currently marketed products and a portfolio of additional product candidates based on marketed drug compounds. Cornerstone also generates revenue from the sale of six marketed product lines that include products that it does not promote. Two of these six product lines are promoted by third parties, and four of these product lines are not promoted by Cornerstone or any third party. Cornerstone recognized net revenues of \$9.4 million in the three months ended March 31, 2008, \$28.1 million in 2007, \$22.1 million in 2006 and \$17.5 million in 2005.

Cornerstone actively promotes the following four respiratory products because it believes they are most responsive to promotional efforts: SPECTRACEF and three ALLERX Dose Pack products. SPECTRACEF is an oral antibiotic indicated for the treatment of mild to moderate infections caused by pathogens associated with particular respiratory tract infections. Cornerstone's three ALLERX Dose Pack products are oral tablets indicated for the temporary relief of symptoms associated with allergic rhinitis. These four promoted products generated aggregate net sales of \$6.5 million in the three months ended March 31, 2008 and \$20.4 million in 2007. The products that Cornerstone does not promote generated additional aggregate net revenues of \$2.9 million in the three months ended March 31, 2008 and \$7.0 million in 2007.

Cornerstone's product development pipeline includes the following three SPECTRACEF line extensions: a 400 mg dose tablet, a once daily dosage tablet and an oral suspension for the pediatric market. Cornerstone's product development pipeline also includes the following three additional product candidates: a methscopolamine and antihistamine combination product candidate for the treatment of the symptoms of allergic rhinitis and two extended-release antitussive, or cough suppressant, combination product candidates. Cornerstone believes that it can substantially mitigate the risks and uncertainties and reduce the time and costs typically associated with new drug development by utilizing Section 505(b)(2) of the FDCA, or by filing sNDAs or ANDAs with the FDA for approval of most of its product candidates. These development pathways provide the potential for expedited development of new formulations of existing compounds because they allow Cornerstone to rely in part on the findings of safety and efficacy of products already approved by the FDA in support of Cornerstone's applications for approval of new or improved formulations. In situations in which it deems appropriate, Cornerstone may choose to develop new formulations of existing compounds that require Cornerstone to conduct new clinical trials to obtain FDA marketing approval. If clinical trials are required in connection with approval of a product candidate, the new formulation may qualify for a three-year period of marketing exclusivity in the United States under the Hatch-Waxman Act. Cornerstone has submitted an sNDA to the FDA for its SPECTRACEF 400 mg line extension and expects to submit applications for approval to the FDA for each of its other current product candidates by the end of 2010.

### Strategy

Cornerstone's goal is to become a leading specialty pharmaceutical company that acquires, develops and commercializes significant products for the respiratory market. Key elements of Cornerstone's strategy to achieve this

goal include the following:

***Grow Product Revenue through a Specialty Sales Force Focused on the Respiratory Market.***

Cornerstone intends to increase revenue from product sales by using its commercial resources, including its specialty sales force, to target respiratory specialists and primary care physicians who are high-prescribers of respiratory products. By concentrating its resources on the respiratory market, Cornerstone believes that it can

increase its profile among prescribers, maximize the sales of its current products and enhance its ability to acquire additional products and product candidates. Cornerstone expects that revenue from sales of its products will be a significant source of funds for product acquisition, development and commercialization.

***Acquire Rights to Under-Promoted, Patent-Protected, Branded Respiratory Pharmaceutical Products.***

Cornerstone continues to seek to expand its product portfolio through the acquisition of rights to FDA-approved respiratory pharmaceutical products with well-established safety and efficacy profiles and projected annual sales potential that large pharmaceutical companies may view as insufficient to justify the time required and the investment necessary to promote with a large sales force. Cornerstone believes that its experience and relationships in the specialty pharmaceutical industry will allow it to identify and acquire products that are under-promoted and would benefit from a focused sales and marketing effort using Cornerstone's commercial resources. Since inception, Cornerstone has acquired rights to eight marketed product lines through its business development network and capabilities.

***Implement Life Cycle Management Strategies.***

Cornerstone expects to continue its efforts to implement life cycle management strategies to maximize the potential value of its currently marketed products, newly acquired products and product candidates that are currently in development. These strategies involve securing FDA approval for additional indications for existing products and developing line extensions in the form of new dosages and formulations of products that offer improvements in patient convenience, compliance or safety. In the case of SPECTRACEF, for example, Cornerstone has submitted an sNDA with the FDA for a 400 mg tablet for twice daily dosing of SPECTRACEF that Cornerstone believes would improve patient convenience as compared to the current dosing of two 200 mg tablets twice daily. A key aspect of this strategy involves the use of proprietary drug delivery and formulation technologies, such that, if approved, the new products may have patent protection or market exclusivity while being commercialized.

***Pursue Strategic Relationships on a Selective Basis for Product Development or Commercialization.***

Cornerstone has entered into and may seek to enter into additional strategic relationships with third parties in order to facilitate the development and commercialization of its products and product candidates. In particular, Cornerstone expects to enter into arrangements that provide it with access to drug delivery and formulation technologies if Cornerstone determines that it is cost effective to do so given the anticipated return on its investment. In addition, Cornerstone has entered into and may seek to enter into additional co-promotion arrangements to enhance its promotional efforts and, therefore, sales of its products. By entering into agreements with pharmaceutical companies that have experienced sales forces with strong management support, Cornerstone can reach health care providers in areas where it has limited or no sales force representation.

**Marketed Products**

Cornerstone currently actively promotes four of its marketed products. The following table sets forth additional information regarding Cornerstone's currently marketed products that it actively promotes.

<b>Promoted Product</b>	<b>Cornerstone Launch Date</b>	<b>Active Pharmaceutical Ingredient(s)</b>	<b>Primary Indication</b>	<b>2007 Net Sales (In thousands)</b>
SPECTRACEF	November 2006	Cefditoren	Treatment of mild to moderate infections that are caused by susceptible strains of microorganisms in community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis, pharyngitis and tonsillitis and uncomplicated skin and skin-structure infections	\$6,886
ALLERX Dose Pack	February 2005(1)	<u>AM dose:</u>  Pseudoephedrine and methscopolamine  <u>PM dose:</u>  Phenylephrine, chlorpheniramine and methscopolamine	Temporary relief of symptoms associated with allergic rhinitis	11,103
ALLERX Dose Pack DF (decongestant-free)	August 2006	<u>AM dose:</u>  Chlorpheniramine and methscopolamine  <u>PM dose:</u>  Chlorpheniramine and methscopolamine	Temporary relief of symptoms associated with allergic rhinitis	967
ALLERX Dose Pack PE	September 2006	<u>AM dose:</u>  Phenylephrine and methscopolamine	Temporary relief of symptoms associated with allergic rhinitis	1,439

PM dose:

Phenylephrine,  
chlorpheniramine and  
methscopolamine

(1) ALLERX Dose Pack was reformulated in February 2008 as ALLERX 10 Dose Pack/ALLERX 30 Dose Pack.

Cornerstone's marketed products that it does not promote generated additional aggregate net revenues of \$7.0 million in 2007.

***SPECTRACEF***

*Overview*

SPECTRACEF, an antibiotic administered orally in tablet form, is a third generation cephalosporin with the API cefditoren pivoxil, a semi-synthetic cephalosporin. SPECTRACEF is indicated for the treatment of mild to moderate infections in adults and adolescents 12 years of age or older that are caused by pathogens associated

with particular respiratory tract infections, including community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis, pharyngitis and tonsillitis and uncomplicated skin and skin-structure infections. Cornerstone's net sales of SPECTRACEF were \$6.9 million in 2007.

#### *Market Opportunity and Other Treatment Options*

According to a 2006 Datamonitor report, each year an average of approximately 88 million patients in the United States are diagnosed with respiratory tract infections, including approximately 25 million with acute exacerbations of chronic bronchitis, 22 million with acute bacterial sinusitis and 19 million with community-acquired pneumonia. According to this Datamonitor report, physicians typically select respiratory tract infection treatments empirically without prior identification of the specific pathogen causing the infection, although antibiotic therapy is the most common form of treatment regardless of whether the bacterial pathogen can be identified. If the specific pathogen has not been identified, health care providers sometimes choose which class of antibiotic to prescribe based on the most likely pathogen causing the infection based on the patient's symptoms.

The U.S. oral antibiotic market is fairly fragmented, with approximately 40 branded products and more than 50 generic products. Pharmacists typically fill prescriptions for antibiotics with generic products when available. According to Wolters Kluwer Health, a third-party provider of prescription data, in 2007, the U.S. oral solid antibiotic market generated approximately 220 million prescriptions, including approximately 44 million for macrolides, such as generic formulations of Pfizer Inc.'s Zithromax® (azithromycin) and Abbott Laboratories, Inc.'s Biaxin® (clarithromycin), approximately 38 million for quinolones, such as Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Levaquin® (levofloxacin) and generic formulations of Bayer AG's Cipr® (ciprofloxacin), and approximately 8 million for second and third generation cephalosporins, such as SPECTRACEF and Shionogi USA, Inc.'s Ceda® (ceftibuten) and generic formulations of Abbott Laboratories, Inc.'s Omnicef® (cefdinir), Pharmacia and Upjohn Company, Inc.'s Vantin® (cefepodoxime), GlaxoSmithKline plc's Ceftin® (cefuroxime), Bristol-Myers Squibb Company's Cefz® (cefprozil) and Eli Lilly & Company's Ceclor® (cefaclor). The only branded oral solid cephalosporin products currently without generic competition in the United States are SPECTRACEF, Cedax and Lupin Pharmaceuticals, Inc.'s Supra® (cefixime), which was recently re-introduced.

Macrolides generally are broad spectrum, have a low incidence of side effects and have convenient dosing regimens. However, macrolides can be associated with severe allergic reactions and interactions with many other commonly prescribed drugs that can affect potency. In addition, *Streptococcus pneumoniae*, a bacterium causing lung infections, displays a high incidence of resistance to macrolide antibiotics. Quinolones generally are considered safe and efficacious overall and have convenient dosing regimens. Quinolones also have multiple interactions with commonly prescribed drugs, cannot be used in children and have been associated with tendon rupture and photosensitivity adverse reactions. Cephalosporins, including SPECTRACEF, generally cause few side effects. Common side effects are gastrointestinal in nature and are mild and transient.

Cephalosporins are classified in the United States based on their spectrum of activity against different types of bacteria. Bacteria are broadly classified into two categories based on the composition of their cell wall structure: gram-positive or gram-negative. In general, cephalosporins developed more recently as follow-on products to the first generation of cephalosporins approved for marketing, commonly referred to as second and third generation cephalosporins, have greater activity against gram-negative bacteria than earlier generations, but decreasing activity against gram-positive bacteria. First generation cephalosporins have good activity against gram-positive bacteria, including *Staphylococcus aureus*, a bacterium associated with skin infections, and *Streptococcus pyogenes*, a bacterium associated with pharyngitis and tonsillitis. Second generation cephalosporins have greater activity against gram-negative bacteria, such as *Haemophilus influenzae*, but also retain some activity against gram-positive bacteria, including *Staphylococcus aureus* and *Streptococcus pyogenes*. Second generation cephalosporins also have some activity against bacteria, such as *Haemophilus influenzae* and *Moraxella catarrhalis*, that produce  $\beta$ -lactamase, an

enzyme that is able to destroy some antibiotics before they can exert their effects on the bacteria. Third generation cephalosporins have even greater activity against a broad spectrum of gram-negative bacteria, such as *Haemophilus influenzae* and



*Moraxella catarrhalis*, including strains of bacteria that produce  $\beta$ -lactamase, but often have decreased activity against gram-positive bacteria.

Cornerstone believes that SPECTRACEF currently is the only branded second or third generation oral solid cephalosporin product being actively promoted to health care providers in the adult respiratory market, although Suprax is being promoted within the pediatric market by Lupin Pharmaceuticals, Inc.'s specialty sales force.

#### *Benefits of SPECTRACEF*

SPECTRACEF is effective against several common respiratory pathogens, including the three most prevalent pathogens in respiratory tract infections as reported in the 2006 Datamonitor report, *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*. In two previously conducted and published clinical trials, cefditoren, present in SPECTRACEF as cefditoren pivoxil, demonstrated superior potency as compared to cefdinir, cefuroxime and cefprozil against community-acquired *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*.

#### *Proprietary Rights*

Cornerstone has an exclusive license from Meiji to market SPECTRACEF and related product candidates in the United States under both an issued U.S. patent with claims to the composition of matter of the API in SPECTRACEF, cefditoren pivoxil, and an issued U.S. patent with claims to the formulation of products like SPECTRACEF that contain a mixture of cefditoren pivoxil with a water soluble casein salt. The composition of matter patent expires in April 2009 and the formulation patent expires in 2016. Cornerstone also has licensed from Meiji the U.S. trademark rights to SPECTRACEF.

### **ALLERX**

#### *Overview*

Cornerstone's ALLERX Dose Pack products are oral tablets indicated for the temporary relief of symptoms associated with allergic rhinitis. Each ALLERX Dose Pack product contains the antihistamine chlorpheniramine, a choice of decongestant, including an option without a decongestant, and methscopolamine, an anticholinergic, or drying agent, which provides additional symptomatic relief by drying up the mucosal secretions associated with allergic rhinitis. Cornerstone's net sales of ALLERX Dose Pack products were \$13.5 million in 2007.

#### *Market Opportunity and Other Treatment Options*

The American Academy of Allergy, Asthma & Immunology, or AAAAI, defines rhinitis as an inflammation of the mucous membranes of the nose with symptoms of sneezing, itching, nasal discharge and congestion. Rhinitis can be allergic, nonallergic or both. Seasonal allergic rhinitis is caused by substances that trigger allergies, called allergens, and is sometimes referred to as hay fever.

According to the Centers for Disease Control and Prevention, or CDC, allergic rhinitis is believed to be responsible for approximately 14.1 million physician visits annually. According to a January 2006 Allergies in America survey, approximately 69% of patients with allergic rhinitis had taken medication for their nasal allergies in the prior four weeks, including 45% who took prescription medication. The survey also reported that 40% of patients surveyed indicated that nasal allergies had a lot or a moderate amount of impact on their daily life, compared with only 33% of patients who indicated that nasal allergies had little or no impact on their daily life.

According to the Allergies in America survey, allergies contribute to an average productivity loss of 25% among workers who suffer from allergies on days when their allergies are at their worst, and allergies resulted in missed workdays for 30% of sufferers in the past year.

The cough, cold and allergy market is very fragmented with hundreds of brands and even more generics. This market includes prescription and over-the-counter antihistamine and antihistamine combination products. First generation antihistamines are widely available and have been used for more than 50 years. They are associated with the side effect of sedation, which can interfere with the patient's quality of life. Some first generation antihistamines, such as chlorpheniramine, also exhibit some anticholinergic effects. Second generation antihistamines were introduced because they are less sedating than first generation antihistamines, but some second generation antihistamines have been linked to cardiac risks. Third generation antihistamines, which are metabolites of second generation antihistamines, are less sedating than first generation antihistamines and have not been associated with cardiac risks. Unlike first generation antihistamines, neither second generation nor third generation antihistamines exhibit anticholinergic effects. In the January 2006 Allergies in America survey, 62% of allergy sufferers reported a runny nose and 61% of allergy sufferers reported post-nasal drip as usually extremely or moderately bothersome during allergy attacks.

First generation prescription antihistamine and antihistamine combination products include Capellon Pharmaceuticals, Ltd.'s Rescon MX (chlorpheniramine, methscopolamine and phenylephrine), Poly Pharmaceuticals, Inc.'s Poly Hist Forte® (chlorpheniramine, phenylephrine and pyrillamine) and Laser Pharmaceuticals, LLC's Dallergey® (phenylephrine, chlorpheniramine and methscopolamine). Over-the-counter products include well known brands such as McNeil-PPC, Inc.'s Zyrtec® (cetirizine hydrochloride) and Schering-Plough Corporation's Claritin® (loratadine), McNeil-PPC, Inc.'s Benadryl® (diphenhydramine) and Schering-Plough Corporation's Chlor-Trimeton® (chlorpheniramine). According to Wolters Kluwer Health, in 2007, oral solid first generation antihistamine and antihistamine combination products generated approximately 6.6 million prescriptions. The ALLERX Dose Pack family of products is the market leader among branded first generation antihistamine and antihistamine combination products, generating approximately 284,000 prescriptions in 2007.

In addition to pharmacotherapy, such as antihistamines and decongestants, there are two other principal treatment options for allergic rhinitis: allergen avoidance and immunotherapy.

According to AAAAI, allergen avoidance is the best treatment, but it is often difficult to avoid the allergy trigger. Immunotherapy, commonly referred to as allergy shots, is a treatment that stimulates the immune system to fight allergies through an immunization procedure beginning with injections of purified extract substances that are causing the allergic reactions. Immunotherapy can be very effective and can decrease the sensitivity of the patient to allergens, but it is time consuming for the patient and can be costly.

Antihistamine therapy typically does not help with congestion, and first generation antihistamines are associated with the side effect of sedation. Decongestants aid with the symptom of congestion but do not help block histamines and are commonly associated with the side effects of insomnia, anxiety and increased heart rate.

#### *Benefits and Description of ALLERX Dose Packs*

ALLERX Dose Packs use a patented dosing regimen and are designed so that side effects, such as insomnia with decongestants and drowsiness with first generation antihistamines, to the extent they are experienced, are most likely to occur at times that these side effects do not inconvenience the patient.

Cornerstone currently markets the following ALLERX Dose Pack products.

#### *ALLERX 10 Dose Pack/ALLERX 30 Dose Pack*

These ALLERX Dose Pack products are available in ten-day and 30-day regimens and consist of a morning, or AM, dose and an evening, or PM, dose. The AM dose contains 120 mg of the decongestant pseudoephedrine, which also

helps patients stay alert during the day, and 2.5 mg of the drying agent methscopolamine. The PM dose contains 8 mg of the antihistamine chlorpheniramine, which helps patients sleep better at night by relieving their symptoms and making them drowsy, 10 mg of the decongestant phenylephrine and 2.5 mg of methscopolamine.

*ALLERX Dose Pack DF/ALLERX Dose Pack DF 30*

ALLERX Dose Pack DF is a decongestant-free dosing regimen suitable for patients who cannot tolerate a decongestant but need the antihistamine and drying agent to relieve their symptoms. ALLERX Dose Pack DF is available in ten-day and 30-day regimens and consists of an AM dose and a PM dose. The AM dose contains 4 mg of the antihistamine chlorpheniramine and 2.5 mg of the drying agent methscopolamine. The PM dose contains 8 mg of chlorpheniramine and 2.5 mg of methscopolamine.

*ALLERX Dose Pack PE/ALLERX Dose Pack PE 30*

ALLERX Dose Pack PE substitutes the decongestant phenylephrine for pseudoephedrine in the AM dose. ALLERX Dose Pack PE may be preferred by physicians who prefer phenylephrine or who are concerned that products containing pseudoephedrine have widely reported by law enforcement personnel as having been used as component ingredients for the illegal manufacture of methamphetamines. It is also suitable for patients who cannot tolerate pseudoephedrine. ALLERX Dose Pack PE is available in ten-day and 30-day regimens and consists of an AM dose and a PM dose. The AM dose contains 40 mg of phenylephrine and 2.5mg of the drying agent methscopolamine. The PM dose contains 10 mg of phenylephrine, 8 mg of the antihistamine chlorpheniramine and 2.5mg of methscopolamine.

*Proprietary Rights*

Cornerstone has an exclusive license from Pharmaceutical Innovations, LLC to market ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30 within the United States under an issued U.S. patent with claims to a prepackaged, therapeutic dosing regimen that includes a less sedating first dose containing a nasal decongestant, a second dose containing an antihistamine and an attenuated dosage of nasal decongestant, indicia for distinguishing between the first and second doses, administration instructions that teach the coordinated use of the first and second doses and a pharmaceutical dispensing container containing the first and second doses and incorporating the indicia and coordinating instructions. This patent expires in 2021. On June 13, 2008, the U.S. Patent and Trademark Office received a request from Vision Pharma, LLC, or Vision, to re-examine this patent. These re-examination proceedings are more fully discussed in the section entitled Legal Proceedings beginning on page 200 of this proxy statement/prospectus.

In addition, Cornerstone has applied for a U.S. patent that, if issued, would include claims to ALLERX Dose Pack DF s and ALLERX Dose Pack DF 30 s AM and PM dosing regimen and method of treating a rhinitic condition using an antihistamine and an anticholinergic in both doses. This patent application has been published and is currently pending. If issued, this patent would expire in 2026.

**Other Products**

***HYOMAX***

*Overview*

HYOMAX is a product line of three antispasmodic medications containing the API hyoscyamine sulfate, an anticholinergic, which may be prescribed for functional intestinal disorders to reduce symptoms such as those seen in mild dysenteries and diverticulitis. HYOMAX can also be used to control gastric secretion, visceral spasm and hypermotility in cystitis, pylorospasm and associated abdominal cramps. Along with appropriate analgesics, HYOMAX may be prescribed for symptomatic relief of biliary and renal colic and as a drying agent in the relief of symptoms of acute rhinitis. HYOMAX products may also be used as adjunctive therapy in the treatment of peptic

ulcer and irritable bowel syndrome, acute enterocolitis and other functional gastrointestinal disorders. Cornerstone launched the first HYOMAX product, HYOMAX SL 0.125 mg tablets, in May 2008, followed by HYOMAX SR 0.375 mg tablets and HYOMAX FT 0.125 mg chewable melt tablets in June 2008.

### *Market Opportunity and Other Treatment Options*

Antispasmodics are often a first-line treatment for patients with irritable bowel syndrome, or IBS, because they offer a safe, cost-effective method of relieving abdominal pain and diarrhea by preventing or slowing contractions in the bowel.

According to the American Academy of Family Physicians, 10% to 15% of the U.S. population is affected with IBS to some degree. According to the American Physical Therapy Association, more than 17 million Americans have urinary incontinence, although only 15% seek treatment. Patients with urinary incontinence may find that antispasmodics relax the bladder muscle and relieve spasms.

The U.S. antispasmodic market is fairly fragmented with approximately 30 branded products and 20 generic products. According to Wolters Kluwer Health, in 2007, in the United States the antispasmodic market generated approximately 25 million prescriptions, including approximately 16 million for urinary incontinence antispasmodics, such as Pfizer Inc.'s Detrol<sup>®</sup> LA (tolterodine tartrate), Astellas Pharmaceuticals, Inc. and GlaxoSmithKline's VESICAR<sup>®</sup> (solifenacin) and the generic formulations of Ortho-McNeil Pharmaceutical, Inc.'s Ditropan<sup>®</sup> and Ditropan<sup>®</sup> XL (oxybutynin), approximately 3.6 million for 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) and approximately 4.4 million for belladonna and derivatives gastrointestinal antispasmodics, such as HYOMAX, and generic formulations of Alaven Pharmaceutical LLC's Levsin<sup>®</sup> (hyoscyamine sulfate) and Levbid<sup>®</sup> (hyoscyamine sulfate) products and of PBM Pharmaceuticals' Donnatal<sup>®</sup> (belladonna alkaloids/phenobarbital). All brands in the belladonna and derivatives gastrointestinal antispasmodics market have a generic formulation. Some newer products for IBS, such as Prometheus Laboratories, Inc.'s Lotronex<sup>®</sup> (alosetron) and Novartis Pharmaceuticals Corporation's Zelnorm<sup>®</sup> (tegaserod), have been subject to FDA risk assessment. Lotronex was introduced and voluntarily withdrawn from the market in 2000 due to concerns of severity and number of adverse results from the use of the product, but was reintroduced to the market in 2002 after agreement with the FDA to institute a Patient-Physician Agreement program. Zelnorm was introduced to the market in 2002 and similarly voluntarily withdrawn from the market in 2007 after findings of an increased risk of serious cardiovascular adverse events associated with the use of the drug.

### *Benefits of HYOMAX*

Once absorbed, HYOMAX disappears rapidly from the blood and is distributed throughout the entire body. The majority of hyoscyamine sulfate is excreted in the urine unchanged within the first 12 hours and only traces of hyoscyamine sulfate are found in the breast milk of nursing mothers. HYOMAX offers patients a cost-effective treatment option for a variety of gastrointestinal problems, such as IBS and urinary incontinence and may be preferred by physicians concerned about adverse events associated with newer products such as Zelnorm.

### *Proprietary Rights*

Cornerstone has an exclusive license from Sovereign Pharmaceuticals, Ltd., or Sovereign, to market and distribute its three hyoscyamine sulfate products in the United States through April 2011. Cornerstone filed for the trademark to HYOMAX in May 2008 for use in connection with marketing this product line.

### **ALLERX**

#### **ALLERX-D**

ALLERX-D contains 120 mg of the decongestant pseudoephedrine and 2.5 mg of the drying agent methscopolamine. Packaged in bottles, ALLERX-D provides patients symptomatic relief of the symptoms of allergic rhinitis without an

antihistamine.



*ALLERX Suspension*

ALLERX Suspension is an oral, liquid decongestant and antihistamine combination that is indicated for patients six years of age or older for symptomatic relief of the nasal inflammation and nasal congestion associated with the common cold, sinusitis and other upper respiratory tract conditions. Each 5 ml dose contains 7.5 mg of the decongestant phenylephrine tannate and 3 mg of the antihistamine chlorpheniramine tannate.

**DECONSAL**

*DECONSAL CT Tannate Chewable Tablets*

DECONSAL CT Tannate Chewable Tablets are antihistamine and nasal decongestant combination chewable tablets for oral administration. DECONSAL CT Tannate Chewable Tablets contain 10 mg of the decongestant phenylephrine and 16 mg of the antihistamine pyrillamine.

*DECONSAL DM Tannate Chewable Tablets*

DECONSAL DM Tannate Chewable Tablets are antihistamine, nasal decongestant and antitussive combination chewable tablets for oral administration. DECONSAL DM Tannate Chewable Tablets contain 10 mg of the decongestant phenylephrine, 16 mg of the antihistamine pyrillamine and 15 mg of the antitussive dextromethorphan.

**BALACET 325**

BALACET 325 is indicated for the relief of mild to moderate pain, either when pain is present alone or when it is accompanied by a fever. BALACET 325 contains 100 mg of propoxyphene napsylate and 325 mg of acetaminophen. Cornerstone licensed rights to the formulation of BALACET 325 from Vintage Pharmaceuticals, LLC, or Vintage, in 2004. Cornerstone's net sales of BALACET 325 were \$4.4 million in 2007. BALACET 325 is currently promoted by Atley Pharmaceuticals under a co-promotion agreement with Cornerstone.

**EXTENDRYL**

The EXTENDRYL® respiratory product line consists of eight products that treat various cough, cold and allergy symptoms. This product line is currently marketed by Auriga Laboratories, Inc., or Auriga, under a license arrangement with Cornerstone.

**APAP 500**

APAP 500 is a generic formulation of Xanodyne Pharmaceuticals, Inc.'s Darvocet a500 and indicated for the relief of mild to moderate pain. Each tablet contains 100 mg of propoxyphene napsylate and 500 mg of acetaminophen.

## Product Development Pipeline

Cornerstone's product development pipeline consists of three SPECTRACEF line extensions and a portfolio of additional product candidates based on marketed drug compounds. The following table sets forth additional information regarding Cornerstone's product candidates.

<b>Product Candidate</b>	<b>Regulatory Status</b>	<b>Therapeutic Class</b>	<b>Method of Administration</b>	<b>Primary Indication(s)</b>
Spectracef Line Extensions SPECTRACEF 400 mg	sNDA submitted	Antibiotic	Oral tablet Twice-daily dosing	Acute bacterial exacerbation of chronic bronchitis; community-acquired pneumonia
SPECTRACEF Once Daily	NDA submission targeted in 2010	Antibiotic	Oral tablet Once-daily Dosing	Acute bacterial exacerbation of chronic bronchitis
SPECTRACEF Suspension	NDA submission for pharyngitis and tonsillitis targeted in 2009; sNDA submission for acute otitis media targeted in 2010	Antibiotic	Oral suspension	Pharyngitis and tonsillitis; acute otitis media
Other Product Candidates				
CBP 058	NDA submission targeted in 2010	Antihistamine and anticholinergic combination	Oral tablet	Temporary relief of symptoms associated with allergic rhinitis
CBP 067	Regulatory submission targeted in 2009	Antihistamine and antitussive combination	Oral suspension	Temporary relief of symptoms associated with cough and upper respiratory symptoms associated with allergies or a cold
CBP 069	Regulatory submission targeted in 2009	Antihistamine and antitussive combination	Oral suspension	Temporary relief of symptoms associated with cough and upper respiratory symptoms associated with allergies or a cold

### *SPECTRACEF Line Extensions*

#### *Overview*

SPECTRACEF is an integral part of Cornerstone's current sales strategy, as well as its sales growth strategy for the future. To protect and expand SPECTRACEF's market share, Cornerstone is developing SPECTRACEF 400 mg, a higher dose tablet for the adult market, Spectracef Once Daily, a new oral solid dosage form, and SPECTRACEF Suspension, an oral suspension for the pediatric market.

*SPECTRACEF 400 mg*

SPECTRACEF 400 mg is a single 400 mg tablet, twice-daily dosage of SPECTRACEF for which Cornerstone has submitted an sNDA to the FDA. Cornerstone believes that patients will find taking one 400 mg tablet twice daily to be more convenient than taking two SPECTRACEF 200 mg tablets twice daily. If approved, Cornerstone expects that SPECTRACEF 400 mg will be indicated for acute bacterial exacerbation of chronic bronchitis and community-acquired pneumonia.

### *SPECTRACEF Once Daily*

SPECTRACEF Once Daily is a single tablet, once-daily dosage of SPECTRACEF. Cornerstone expects to commence clinical trials in the fourth quarter of 2008 to evaluate the pharmacokinetic profile of a formulation of SPECTRACEF Once Daily developed by Patheon Inc. If the results of these pharmacokinetic trials are favorable, Cornerstone expects to commence two clinical trials in the first quarter of 2009 to evaluate the safety and efficacy of this product candidate designed to form the basis for an NDA submission to the FDA in 2010 for the treatment of acute bacterial exacerbation of chronic bronchitis. Cornerstone anticipates that, if approved based on the results of these clinical trials, the FDA will grant SPECTRACEF Once Daily a three-year period of marketing exclusivity under the Hatch-Waxman Act.

Cornerstone believes that the once-daily dosage of this product candidate would be more convenient for patients than taking SPECTRACEF twice daily and would increase compliance. Among oral solid cephalosporins, only Cedax and Suprax have a once-daily dosage. Most macrolides and quinolones also have a once-daily dosage option.

### *SPECTRACEF Suspension*

SPECTRACEF Suspension is an oral, liquid suspension of SPECTRACEF. Cornerstone expects to submit an NDA in 2009 for use of this product candidate by children with pharyngitis or tonsillitis based on the results of a number of previously conducted clinical trials. Two of these clinical trials compared the safety and efficacy of orally administered cefditoren pivoxil with an FDA-approved product, penicillin VK, using a non-inferiority design. Each clinical trial was a Phase III, randomized, double-blind, active-controlled, parallel-group, multicenter study of outpatients with streptococcal pharyngitis or tonsillitis. In the first clinical trial, 503 patients received either cefditoren pivoxil or penicillin VK. Of these, a total of 364 patients were considered microbiologically evaluable for efficacy at a post-therapy visit and 352 patients were microbiologically evaluable for efficacy at a subsequent follow-up visit. All 503 patients were included in the safety analyses. In the second clinical trial, 508 patients received either cefditoren pivoxil or penicillin VK. Of these, a total of 364 patients were considered microbiologically evaluable for efficacy at a post-therapy visit and 355 patients were microbiologically evaluable for efficacy at a subsequent follow-up visit. All 508 patients were included in the safety analyses. In each of these trials, cefditoren pivoxil was well tolerated with no significant adverse events reported. In the first trial, both treatment regimens were effective in resolving the clinical signs and symptoms of streptococcal pharyngitis or tonsillitis, but cefditoren pivoxil was statistically superior to penicillin VK in eradicating *Streptococcus pyogenes*. In the second trial, cefditoren pivoxil was equivalent to penicillin VK in resolving the clinical signs and symptoms of streptococcal pharyngitis or tonsillitis and in eradicating *Streptococcus pyogenes*.

In addition, Cornerstone expects to commence additional clinical trials in 2009 for SPECTRACEF Suspension in acute otitis media and submit an sNDA for this indication in 2010. Cornerstone is designing these clinical trials as superiority, randomized studies of patients with acute otitis media to evaluate the safety and efficacy of SPECTRACEF Suspension. A superiority trial must show that the test product is statistically better than the comparator, which may be placebo. If its NDA is approved, Cornerstone will have the option of launching SPECTRACEF suspension for the pharyngitis and tonsillitis indications while the clinical trials in acute otitis media are ongoing. Cornerstone anticipates that, if approved based on the results of these clinical trials, the FDA will grant SPECTRACEF Suspension a three-year period of marketing exclusivity under the Hatch-Waxman Act for acute otitis media.

According to Wolters Kluwer Health, second and third generation oral cephalosporin suspensions generated approximately 7.8 million prescriptions in 2007 and approximately \$750 million in sales, including suspension products containing cefdinir that generated approximately 5.6 million prescriptions and approximately \$580 million in sales.

According to Wolters Kluwer Health, during the 54 week period ending May 16, 2008, pediatric specialists generated approximately 5 million second and third generation oral cephalosporin suspension prescriptions, or 64% of these prescriptions, and family practice specialists generated approximately 1.4 million prescriptions, or approximately 17% of these prescriptions.

### *Proprietary Rights*

SPECTRACEF 400 mg, SPECTRACEF Once Daily and SPECTRACEF Suspension are covered by the same U.S. patents as SPECTRACEF 200 mg. Meiji also has applied for a U.S. patent that, if issued, would include claims to enhanced oral absorptivity for SPECTRACEF Once Daily. This patent application has been published and is currently pending. If issued, this patent would expire in 2023. Cornerstone's rights to market and develop SPECTRACEF 400 mg, SPECTRACEF Once Daily and SPECTRACEF Suspension are subject to its license arrangements with Meiji.

### *Other Product Candidates*

#### *Methscopolamine/Antihistamine Product Candidate CBP 058*

#### *Overview and Development Status*

CBP 058 is a combination methscopolamine and antihistamine product candidate that Cornerstone is developing for the treatment of the symptoms of allergic rhinitis. Cornerstone has filed an IND for this product candidate and met with the FDA in 2007 to discuss its related development plan. Cornerstone plans to commence clinical trials of this product candidate in the fourth quarter of 2008 and submit an NDA in 2010. If approved, Cornerstone believes this product candidate would be the first FDA-approved product containing methscopolamine with an allergic rhinitis indication.

#### *Market Opportunity and Current Treatment Options*

According to AAAAI, allergic rhinitis has a strong link to other respiratory diseases including chronic sinusitis, middle ear infections, nasal polyps and bronchial asthma. The connection to bronchial asthma has caused great concern among allergists and immunologists. For example, a March 1999 article in *Discover* magazine described an analysis of over 1,200 asthmatics, approximately half of whom had rhinitis and half whom did not, in which those who had both rhinitis and asthma were more likely to have nighttime awakening due to asthma, 19.6 percent compared to 11.8 percent, to miss work because of asthma, 24.1 percent compared to 12.1 percent, and to meet the criteria for moderate to severe asthma, 60.2 percent compared to 51.2 percent. Additionally, asthmatics with rhinitis require more potent medications to control their symptoms. One potential explanation is that severe post-nasal drip triggers episodes of asthma. For example, researchers have found that inflammatory chemicals commonly found in the noses of people with allergic rhinitis drip into the lungs while they sleep, thus causing asthma to worsen.

According to Wolters Kluwer Health, oral solid methscopolamine combination products for the treatment of symptoms of respiratory diseases and allergies generated approximately 1.6 million prescriptions in 2007, representing a growth rate of 15% compared to 2006. In addition, second and third generation antihistamine and antihistamine combination products generated a total of approximately 52 million prescriptions in 2007.

Current treatments for the symptoms of allergic rhinitis consist of both prescription and over-the-counter products. Prescription products include large second generation antihistamine branded families of products, such as Sanofi-Aventis U.S. LLC's Allegra® (fexofenadine), third generation antihistamine branded families of products, such as UCB, Inc. and Sanofi-Aventis U.S. LLC's Xyzal® (levocetirizine) and Schering-Plough Corporation's Clarinex® (desloratadine), and first generation antihistamine and antihistamine combination products, most of which are generic formulations. Over-the-counter products include first generation antihistamines, such as McNeil-PPC, Inc.'s Benadryl® (diphenhydramine) and Schering-Plough Corporation's Chlor-Trimeton® (chlorpheniramine), and second generation antihistamines, such as Claritin and Zyrtec.

*Benefits of CBP 058*

If approved, CBP 058 will combine a less sedating antihistamine to combat the histamine released during an allergic reaction with an anticholinergic to relieve symptoms of post-nasal drip and other mucous secretions. This combination of therapies is not currently commercially available in a single tablet. Less sedating second and third generation prescription antihistamines do not have an anticholinergic option, and first generation antihistamine and anticholinergic combination products currently available on the market are more sedating.

Cornerstone anticipates that, if approved based on the results of clinical trials that it plans to conduct, the FDA will grant CBP 058 a three-year period of marketing exclusivity under the Hatch-Waxman Act. In addition, based on FDA precedent with respect to DESI II drugs that are clinically tested and submitted to the FDA for approval, Cornerstone expects that the FDA would require other methscopolamine products, including the first generation antihistamine and methscopolamine combinations currently available, to be removed from the market after a grace period. In such event, Cornerstone believes that CBP 058 would be the only methscopolamine product indicated for allergic rhinitis on the market that physicians could prescribe.

#### *Proprietary Rights*

Cornerstone has licensed the rights to market CBP 058 utilizing the Dynamic Variable Release® technology licensed from Neos. Dynamic Variable Release technology is covered under a pending U.S. patent application that if issued would expire in 2024. This licensed technology allows Cornerstone to formulate CBP 058 with one or more active pharmaceutical ingredients that require immediate activation followed by extended release of the remaining active pharmaceutical ingredients.

#### *Hydrocodone Cough Suppressant Product Candidates CBP 067 and CBP 069*

##### *Overview and Development Status*

CBP 067 and CBP 069 are extended-release antihistamine and antitussive, or cough suppressant, combination product candidates currently in development. Cornerstone plans to submit applications for marketing approval for these product candidates in the first quarter of 2009 and, if approved, commercially launch the product candidates in the fourth quarter of 2009. If approved, these product candidates will compete directly in the hydrocodone cough suppressant market.

##### *Market Opportunity and Current Treatment Options*

Cough can adversely affect quality of life, leading patients to seek medical attention. Health care providers have a variety of treatment options. Non-productive cough is commonly treated with antitussive and antitussive combinations that do not contain an expectorant, such as guaifenesin. Antitussive combination products that treat non-productive coughs typically combine an antitussive, including hydrocodone, codeine or dextromethorphan, with antihistamines, including chlorpheniramine or brompheniramine, or decongestants, including pseudoephedrine or phenylephrine. Dextromethorphan is available in both over-the-counter and prescription formulations. Hydrocodone, a centrally acting opioid antitussive, has been shown to be as effective as codeine but without gastrointestinal side effects.

According to Wolters Kluwer Health, in 2007, there were over 26 million prescriptions generated for oral antitussive and antitussive combinations without an expectorant. Of these, nearly 4.8 million were for Phenergan with codeine, which is available as a generic, and almost 3 million for UCB Pharma's Tussionex® (hydrocodone polistirex and chlorpheniramine polistirex), which is only available as a brand.

On September 28, 2007, the FDA announced its intention to take enforcement action against companies marketing unapproved prescription drug products containing the narcotic hydrocodone. The action did not affect hydrocodone formulations that have FDA approval. Only eight cough suppressants containing hydrocodone were approved by the FDA as of May 31, 2008. Any company marketing unapproved hydrocodone drug products was required to cease manufacturing such products on or before December 31, 2007, and cease further shipment in interstate commerce on or before March 31, 2008, although pharmacies could continue to sell their remaining inventory.



According to Wolters Kluwer Health, U.S. sales of prescription hydrocodone cough suppressants were \$300 million in 2007, with over 9.75 million prescriptions written. Approximately 55% of those prescriptions were for products not approved by the FDA.

In addition, 66% of the sales and 30% of the prescriptions written in 2007 for hydrocodone cough suppressants were generated by Tussionex, an approved extended-release hydrocodone and antihistamine combination. With limited availability of approved hydrocodone products, Tussionex prescriptions have

increased dramatically in 2008. According to Wolters Kluwer Health, in April 2008, the month after the FDA enforcement action went into effect, Tussionex prescriptions grew 34% and sales grew 46% as compared to April 2007. Despite being approved by the FDA in 1987, Tussionex does not face any generic competition and has no patent protection.

#### *Benefits of CBP 067 and CBP 069*

Most antitussive and antitussive combination products that are currently marketed are in an immediate-release formulation, meaning they must be dosed every four to six hours, which can be inconvenient. For example, patients may not be able to sleep through the night because their antitussive is not effective for more than four hours. Cornerstone believes that CBP 067 and CBP 069 could improve patients' quality of life by providing more convenient twice-daily, longer lasting dosing.

#### *Proprietary Rights*

Cornerstone has licensed the rights to market CBP 067 and CBP 069 utilizing the Dynamic Variable Release technology and the Dynamic Time Release Suspension<sup>™</sup> technology of Neos and the drug resin complex technology of Coating Place, Inc., or Coating Place. Cornerstone expects that these licensed technologies will allow Cornerstone to formulate CBP 067 and CBP 069 with one or more active pharmaceutical ingredients that require immediate activation followed by a sustained timed release of the remaining active pharmaceutical ingredients over a 12-hour period. Neos' Dynamic Variable Release technology is covered under a pending U.S. patent application that if issued would expire in 2024. Neos' Dynamic Time Release Suspension technology is covered under a pending U.S. patent application that if issued would expire in 2025. Coating Place's drug resin complex technology is covered under a pending U.S. patent application that if issued would expire in 2025.

### **Sales and Marketing; Co-promotion Agreements**

#### *Sales and Marketing*

Cornerstone has built a commercial organization, consisting at June 30, 2008 of a respiratory-focused sales team that includes 50 sales representatives and a marketing team currently comprised of two fulltime marketing professionals. Cornerstone currently utilizes its sales force to call on high-prescribing, respiratory-focused physicians and key retail pharmacies. Cornerstone believes this highly specialized approach provides it with the opportunity for greater access to this group of health care professionals. It also increases Cornerstone's market coverage and frequency of detailing visits to this target audience. All representatives are required to provide management with quarterly business plans to ensure all resources are being utilized effectively. Cornerstone currently maintains a one to two-week call cycle for all promoted products and records calls into an internal system through its business analytics group.

Cornerstone believes that the current market opportunity for its products and the future opportunity for its pipeline of product candidates, if approved, will likely warrant the need for sales force expansion. Cornerstone expects to commence this expansion as FDA approval of a product candidate is obtained or expected to be obtained in the near future, revenues expand or Cornerstone obtains additional funding.

Cornerstone's marketing group consists of experienced professionals responsible for developing its brand plans. The group also develops strategies and tactical plans for sales force execution. In addition to these marketing personnel, Cornerstone employs a fulltime group of market research and commercial operations professionals responsible for business analytics, commercial technology, sales operations, training and professional development.

Cornerstone seeks to differentiate its products from its competitors by emphasizing the clinical advantages and favorable side effect profile for patients who are suffering from respiratory diseases or allergies. Cornerstone's marketing programs include patient co-payment assistance, health care provider education and information to further support patient compliance. In addition, Cornerstone has established a respiratory advisory board with

varying specialties to assist in developing its corporate strategy for both its products and product candidates. National conventions and publication plans are also integral aspects of Cornerstone's overall marketing plan.

### *Co-promotion Agreements*

Cornerstone seeks to enter into co-promotion arrangements to enhance its promotional efforts and sales of its products. Cornerstone may enter into co-promotion agreements with respect to its products that are not aligned with Cornerstone's respiratory focus or when it lacks sufficient sales force representation in a particular geographic area.

#### *Co-promotion Agreement with SJ Pharmaceuticals*

In March 2007 and June 2007, Cornerstone entered into co-promotion agreements with SJ Pharmaceuticals to co-promote the ALLERX Dose Pack family of products and SPECTRACEF, respectively. Under these agreements, Cornerstone pays SJ Pharmaceuticals fees based on a percentage of the net profits of the ALLERX Dose Pack and SPECTRACEF products sold above a specified baseline based upon prescriptions by assigned, targeted prescribers within assigned sales territories. These targeted prescribers are mutually agreed upon by Cornerstone and SJ Pharmaceuticals prior to the start of each quarter.

SJ Pharmaceuticals' sales representatives are located primarily in the southeastern United States. SJ Pharmaceuticals is required under the co-promotion agreements to maintain a trained sales force of at least 20 representatives to detail ALLERX Dose Pack and SPECTRACEF products and is required to maintain an incentive compensation plan to encourage superior performance by its sales representatives. SJ Pharmaceuticals promotes the ALLERX Dose Pack and SPECTRACEF products to primary care physicians, allergists, otolaryngologists, physician assistants, nurse practitioners, pharmacists and other specialists in SJ Pharmaceuticals' assigned sales territories. Because SJ Pharmaceuticals only promotes to prescribers on its assigned, targeted prescriber list, Cornerstone sales representatives have no overlapping prescribers.

The ALLERX co-promotion agreement expires on March 28, 2010, unless extended by mutual agreement of the parties. The SPECTRACEF co-promotion agreement expires on June 13, 2010, unless extended by mutual agreement of the parties. Each co-promotion agreement can be terminated by either party without cause upon 60 days' advance notice. Additionally, Cornerstone may terminate the SPECTRACEF co-promotion agreement at any time if SJ Pharmaceuticals is unable to increase SPECTRACEF sales above the specified baseline.

#### *Co-promotion Agreement with Atley Pharmaceuticals*

In April 2007, Cornerstone entered into a co-promotion agreement with Atley Pharmaceuticals to co-promote BALACET 325 beginning July 1, 2007. Under the agreement, Cornerstone pays Atley Pharmaceuticals fees based on a percentage of the net profits from sales of BALACET 325 above a specified baseline within assigned sales territories.

Atley Pharmaceuticals' sales representatives are mainly located in the southeastern, southwestern and midwestern United States. Atley Pharmaceuticals is required under the co-promotion agreement to maintain a trained sales force of at least 40 representatives to detail BALACET 325 and an incentive compensation plan to encourage superior performance by its sales representatives. Atley Pharmaceuticals promotes BALACET 325 to pain specialists and primary care providers and other specialties within Atley Pharmaceuticals' assigned sales territories. According to Wolters Kluwer Health, there has been a 35% increase in bottles dispensed from the first half of 2007 to the second half of 2007 within the sales territories where Atley Pharmaceuticals' sales representatives market the product.

The co-promotion agreement expires on April 2, 2010, unless extended by mutual agreement of the parties. Either party may terminate the co-promotion agreement without cause upon 60 days advance notice.

## Trade, Distribution and Reimbursement

### *Trade Sales and Distribution*

Cornerstone's customers consist of drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies in the United States. It primarily sells products directly to drug wholesalers, which in turn distribute the products to retail drug stores, mass merchandisers and grocery store pharmacies. Cornerstone's top three customers, which represented 91% of gross sales in 2007, are all drug wholesalers and are listed below:

Customer	% of Gross Sales		
	2007	2006	2005
Cardinal Health	43.2%	36.7%	45.1%
McKesson	33.7%	37.6%	30.8%
AmerisourceBergen	13.9%	8.5%	9.6%

Consistent with industry practice, Cornerstone maintains a returns policy that allows its customers to return products within a specified period prior and subsequent to the expiration date. Occasionally, Cornerstone may also provide additional discounts to some customers to ensure adequate distribution of its products.

Cornerstone's trade distribution group actively markets Cornerstone's products to authorized distributors through regular sales calls. This group has many years of experience working with various industry distribution channels. Cornerstone management believes that its trade distribution group significantly enhances Cornerstone's commercial performance by ensuring product stocking in major channels across the country; continued follow-up with accounts and monitoring of product performance; successful product launch strategies; and partnering with customers on other value-added programs. Cornerstone's active marketing effort is designed to ensure proper distribution of its products so that patients' prescriptions can be filled with the Cornerstone products that health care professionals prescribe.

Cornerstone relies on DDN, a third party logistics provider, for the distribution of Cornerstone's products to drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies. DDN ships Cornerstone's products from its warehouse in Memphis, Tennessee to Cornerstone customers throughout the United States as orders are placed through Cornerstone's customer service center.

### *Reimbursement*

In the U.S. market, sales of pharmaceutical products depend in part on the availability of reimbursement to the patient from third-party payors, such as government health administration authorities, managed care providers and private insurance plans. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and reviewing different cost savings efforts, which could affect the reimbursement available for Cornerstone's products.

### *Manufacturing*

Cornerstone currently outsources the manufacturing of all of its commercially available products and the formulation development of its product candidates for use in clinical trials to FDA- approved third parties. Cornerstone intends to continue to rely on third parties for its manufacturing requirements. Cornerstone provides regulatory and quality guidance to and oversight of its third-party manufacturers with respect to its products. Cornerstone also provides

regular product forecasts to assist its third-party manufacturers with efficient production planning. Where possible and commercially reasonable, Cornerstone qualifies more than one source for manufacturing and packaging of its products to manage the risk of supply disruptions. In such circumstances, if one of Cornerstone's manufacturers or packagers were unable to supply Cornerstone's needs, Cornerstone would have an alternative source available for those products.

While some of Cornerstone's products do not have an alternative manufacturer qualified due to exclusivity provisions in the respective licensing agreements or based on other commercial considerations, Cornerstone believes there are other suppliers that could serve as replacements for the current manufacturers if the need

arose. However, qualifying such a replacement manufacturer with the FDA could take a significant amount of time, and, as a result, Cornerstone would not be able to guarantee an uninterrupted supply of the affected product to its customers.

Cornerstone has entered into supply agreements with third-party manufacturers and packagers for each of its marketed products. Depending on the finished product presentation, some of its manufacturers also package the product. In other cases, the manufacturer supplies the bulk form of the product and Cornerstone packages the product through a separate third party. Important information about Cornerstone's material manufacturing and packaging agreements is summarized in the following table.

<b>Manufacturer/ Packager</b>	<b>Product</b>	<b>Term of Agreement</b>
Meiji	SPECTRACEF API (cefditoren pivoxil)	October 2006 to September 2016; renews for successive one-year terms unless terminated with six months' prior written notice.
Patheon	SPECTRACEF 200 mg finished product	Product ordered from time to time on a purchase order basis.
Bayer Healthcare	Bulk tablets for the ALLERX Dose Pack family of products	July 2007 to June 2010; renews for successive one-year terms unless terminated by either party with six months' prior written notice.
Legacy Pharmaceutical Packaging, LLC	Trade and sample packaging for ALLERX Dose Pack family of products	March 2006 to February 2011; will renew for one-year terms unless terminated by either party with a written notice 90 days prior to end of the term.
Vintage	BALACET 325	July 2004 to June 2009; renew for one-year terms unless terminated with one year's prior written notice.

Several of Cornerstone's products require the use of active pharmaceutical ingredients regulated by the DEA under the Controlled Substances Act. In these instances, DEA quota requirements regulate the procurement of these active pharmaceutical ingredients and products containing these active pharmaceutical ingredients by the manufacturer and packager. It is the responsibility of each Cornerstone manufacturer and packager to request the necessary quota allocation from the DEA to meet Cornerstone's forecasted production requirements on an annual basis. However, the DEA has significant discretion in deciding how to allocate controlled substance quotas and whether to authorize a quota for Cornerstone. This discretion presents a potential risk to Cornerstone's supply chain. Cornerstone and its suppliers attempt to manage this risk through accurate product planning and timely quota submissions with appropriate allocation justifications to the DEA.

In producing Cornerstone's products, Cornerstone's manufacturers and packagers are also held to the FDA's cGMP requirements and other compliance regulations mandated by the FDA, the DEA and other regulatory authorities.

### **Intellectual Property**

Cornerstone's success depends in part on its ability to obtain and maintain proprietary protection for its product candidates, technology and know-how, to operate without infringing on the proprietary rights of others and to prevent



others from infringing its proprietary rights. Cornerstone's policy is to seek to protect its proprietary position by, among other methods, filing U.S. and foreign patent applications related to its proprietary technology, inventions and improvements that are important to the development of its business and obtaining, where possible, assignment of invention agreements from employees and consultants. Cornerstone also relies on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain its proprietary position.

### ***Patents***

As of June 30, 2008, Cornerstone owned or exclusively licensed a total of five issued U.S. patents and three pending U.S. patent applications. Cornerstone's patent portfolio includes patents and patent applications with claims directed to composition of matter, formulations of its products and product candidates and methods of use of its products and product candidates to treat particular indications.

Other than SPECTRACEF, patent protection is not available for composition of matter claims directed to the active pharmaceutical ingredients of Cornerstone's current products and product candidates. As a result, Cornerstone primarily relies on the protections afforded by its formulation and method of use patents. Method of use patents, in particular, are more difficult to enforce than composition of matter patents because of the risk of off-label sale or use of the subject compounds.

For information about the patents and patent applications that Cornerstone owns or exclusively licenses that it considers to be most important to the protection of its products and product candidates, see *Proprietary Rights* under each of the products and product candidates described above under *Marketed Products* and *Product Development Pipeline*.

### ***Trade Secrets***

Cornerstone may rely, in some circumstances, on trade secrets to protect its technology. However, trade secrets can be difficult to protect. Cornerstone seeks to protect its proprietary technology and processes, in part, by confidentiality agreements with its employees, consultants, scientific advisors and consultants. Cornerstone also seeks to preserve the integrity and confidentiality of its data and trade secrets by maintaining physical security of its premises and physical and electronic security of its information technology systems. While Cornerstone has confidence in these individuals, organizations and systems, agreements or security measures may be breached, and Cornerstone may not have adequate remedies for any such breach. In addition, Cornerstone's trade secrets may otherwise become known or be independently discovered by competitors. To the extent that Cornerstone's consultants, contractors or collaborators use intellectual property owned by others in their work for Cornerstone, disputes may arise as to the rights in related or resulting know-how or inventions.

### ***Trademarks***

Cornerstone uses trademarks on all of its marketed branded products and believes that having distinctive marks is an important factor in marketing these products. Cornerstone has registered with the United States Patent and Trademark Office its ALLERX, DECONSAL and BALACET trademarks, among others. SPECTRACEF is owned by Meiji and licensed to Cornerstone for sales and marketing purposes in the United States.

## **License and Collaboration Agreements**

### ***Meiji SPECTRACEF License and Supply Agreement***

#### *Overview*

On October 12, 2006, Cornerstone entered into a license and supply agreement, as amended on July 27, 2007, with Meiji that grants Cornerstone an exclusive, nonassignable U.S. license to manufacture and sell SPECTRACEF, using cefditoren pivoxil supplied by Meiji, for its currently approved therapeutic indications and to use Meiji's SPECTRACEF trademark in connection with the sale and promotion of SPECTRACEF for its currently approved therapeutic indications. The agreement also extends these rights to additional products and additional therapeutic

indications of products containing cefditoren pivoxil supplied by Meiji that are jointly developed by Meiji and Cornerstone and which Meiji and Cornerstone agree to have covered by the agreement.

### *Fees, Milestones and Royalties*

In consideration for the licenses Meiji granted to Cornerstone, Cornerstone agreed to pay Meiji a nonrefundable license fee of \$6 million in six installments over a period of five years from the date of the agreement. If a generic cefditoren product is launched in the United States prior to October 12, 2011, Cornerstone will be released from its obligation to make any further license fee payments due after the date of launch, unless, as agreed in a July 27, 2007 letter agreement between Cornerstone and Meiji, Cornerstone successfully launches SPECTRACEF 400 mg, SPECTRACEF Once Daily or SPECTRACEF Suspension and sales of these products substantially lessen the generic product's adverse effect on SPECTRACEF sales. If Cornerstone is able to launch one of these SPECTRACEF line extensions and substantially mitigate the effect of generic competition, it will be required to continue paying Meiji a reasonable amount of the license fee as mutually agreed by the parties.

### *Exclusive Supplier and Minimum Purchase Obligation*

The license and supply agreement also requires Cornerstone to make quarterly royalty payments based on the net sales of the cefditoren pivoxil products covered by the agreement. Cornerstone is required to make these payments for a period of ten years from the date the particular product is launched by Cornerstone.

Under the license and supply agreement, Meiji is Cornerstone's exclusive supplier of cefditoren pivoxil. Cornerstone is required to purchase from Meiji the amount of cefditoren pivoxil necessary to support 80% of its targeted annual gross sales of cefditoren pivoxil products for the five-year period ending April 1, 2012 as specified in the agreement. If Cornerstone does not meet its minimum purchase requirement in a given year, Cornerstone must pay Meiji an amount equal to 50% of the shortfall in that year. These minimum purchase requirements cease to apply if a generic cefditoren product is launched in the United States prior to October 12, 2011.

### *Term and Termination*

The initial term of the license and supply agreement expires on April 1, 2017. The agreement will be automatically renewed for additional one-year terms unless either Meiji or Cornerstone gives six months' prior written notice of termination. Meiji may terminate the agreement if Cornerstone undergoes a change in control as defined in the agreement without Meiji's consent, which may not be unreasonably withheld; ceases selling SPECTRACEF for a period of 60 days, unless the cessation is due to a force majeure event or a failure or delay by Meiji in supplying cefditoren pivoxil; or promotes, markets or sells, either directly or indirectly through a third party, any pharmaceutical products in the United States of the same therapeutic class as cefditoren pivoxil. On or after April 1, 2012, Cornerstone may terminate the agreement with 270 days' prior written notice if a generic cefditoren product is launched in the United States that substantially lessens Cornerstone's sales of SPECTRACEF.

### *Joint Product Development*

If either Meiji or Cornerstone desires to develop new products or new therapeutic indications of an existing product under the license and supply agreement, that party must notify the other party, and both parties must then discuss in good faith the joint development of the new product or therapeutic indication and agree on whether the license and supply agreement will cover the new product or therapeutic indication.

### *Letter Agreement and Formulation Agreement*

On July 27, 2007, Meiji and Cornerstone entered into a letter agreement whereby they agreed that SPECTRACEF 400 mg, SPECTRACEF Suspension and SPECTRACEF Once Daily would be covered by the license and supply agreement once Cornerstone receives the necessary FDA approvals for these SPECTRACEF line extensions. The

letter agreement further provides that Cornerstone has the exclusive right to manufacture and sell these SPECTRACEF line extensions in the United States for their approved therapeutic indications and to use the SPECTRACEF trademark in connection with the sale of these SPECTRACEF line extensions for their approved therapeutic indications.

The letter agreement requires Cornerstone to bear all of the development costs for SPECTRACEF 400 mg. Under a further letter agreement dated January 11, 2008, or the formulation agreement, Cornerstone and Meiji agreed on the allocation of expenses related to the development of SPECTRACEF Suspension and SPECTRACEF Once Daily, and Meiji agreed to make payments for the development of these product candidates to Cornerstone in installments through June 30, 2008.

### ***Joint Development Agreement***

On February 11, 2008, Cornerstone and Meiji entered into a joint development agreement, which supplemented the July 27, 2007 letter agreement and the January 11, 2008 formulation agreement. Under the joint development agreement, Meiji granted Cornerstone the exclusive right to develop SPECTRACEF Suspension and SPECTRACEF Once Daily in the United States. Under the joint development agreement, Meiji and Cornerstone agreed on a development plan for SPECTRACEF Suspension and SPECTRACEF Once Daily; agreed that Cornerstone would bear all expenses related to the development of these SPECTRACEF line extensions except as provided in the formulation agreement; and confirmed that, once approved, these SPECTRACEF line extensions would be covered by the license and supply agreement.

The term of the joint development agreement runs concurrently with the term of the license and supply agreement, unless earlier terminated. Either party may terminate the agreement after consultation with the other party and with 30 days prior written notice, if it becomes impossible or impracticable from a reasonable pharmaceutical point of view to continue the development of SPECTRACEF Suspension and SPECTRACEF Once Daily. If Cornerstone terminates the joint development agreement based on impossibility or impracticability from a reasonable pharmaceutical point of view, Cornerstone's rights to SPECTRACEF Suspension and SPECTRACEF Once Daily under the July 27, 2007 letter agreement and the joint development agreement will terminate, and Cornerstone would be required to assist Meiji with further development of those product candidates if so requested by Meiji.

### ***Letter Agreement 2007 Sales Force Expansion***

On July 10, 2007, Cornerstone and Meiji entered into a letter agreement, which supplemented the SPECTRACEF license and supply agreement. Under this letter agreement, Meiji agreed to partially fund sales representative hiring expenses related to the expansion of Cornerstone's sales force that was promoting SPECTRACEF from 35 sales representatives to 100 sales representatives by the end of March 2008, with the amount of Meiji funding dependent on Cornerstone's aggregate gross sales of SPECTRACEF during 2007. In September 2007, Cornerstone added a commission-based sales force to complement its pre-existing sales force. By December 2007, Cornerstone had increased the size of its sales force to 100 sales representatives. Pursuant to this letter agreement, Meiji paid Cornerstone \$1.5 million based on its achievement of gross sales of SPECTRACEF in excess of \$8.0 million during 2007. On May 1, 2008, Cornerstone consolidated all of its sales functions under one national sales director, reduced the size of its sales force and eliminated commission-based compensation for the previous members of its commission-based sales force. As of June 30, 2008, Cornerstone's sales force was comprised of 50 sales representatives.

### ***Pharmaceutical Innovations ALLERX 372 Patent License Agreement***

#### ***Overview***

On August 31, 2006, Cornerstone entered into a license agreement with Pharmaceutical Innovations that, as subsequently amended, provides for an exclusive license in the United States and a nonexclusive license in all other markets to manufacture, package, market, distribute and otherwise exploit ALLERX Dose Pack products that are covered by claims under Pharmaceutical Innovations' U.S. patent 6,843,372, or the 372 Patent, by corresponding

foreign patents and foreign patent applications and by certain Pharmaceutical Innovations know-how related to those ALLERX Dose Pack products. Cornerstone also has the right to sublicense its rights under the license agreement to third parties. The 372 Patent expires May 4, 2021. On June 13, 2008, the U.S. Patent and Trademark Office received a request from Vision to re-examine the 372 Patent. These re-

examination proceedings are more fully discussed in the section entitled "Legal Proceedings" beginning on page 200 of this proxy statement/prospectus.

#### *Royalties*

Cornerstone pays Pharmaceutical Innovations royalties based on net sales per calendar year of each product covered by the licensed Pharmaceutical Innovations patents or know-how. Cornerstone has agreed to a minimum annual royalty payment to Pharmaceutical Innovations throughout the term of the agreement. Royalties are payable with respect to the licensed patents until the earlier of the date all of the licensed patents expire or the date all of the licensed patents are determined to be invalid by a court or other governmental authority and such determination is no longer subject to appeal. Royalties are payable with respect to licensed know-how for a further period of seven years after the expiration of Cornerstone's obligation to pay royalties with respect to the licensed patents.

#### *Term and Termination*

The term of the agreement expires on the seventh anniversary of the earlier of the date that all the licensed patents expire or the date all licensed patents are determined to be invalid by a court or other governmental authority and such determination is no longer subject to appeal. Following expiration of the agreement, Cornerstone has a fully paid, perpetual license to continue to make use of the Pharmaceutical Innovations know-how to manufacture, package, market, distribute and otherwise exploit the ALLERX Dose Pack products covered by claims under the '372 Patent.

#### *Neos Methscopolamine/Antihistamine Product*

In March 2008, Cornerstone entered into a development, license and service agreement with Neos pursuant to which Cornerstone obtained an exclusive license under Neos's patent-pending Dynamic Variable Release technology to develop, manufacture and commercialize a combination methscopolamine and antihistamine product in the United States, subject to obtaining necessary approvals from the FDA. Under the agreement, Neos is responsible for formulation of the licensed product, development and documentation of the manufacturing process for such product, and preparation of the chemistry, manufacturing and controls section of the NDA for such product. Following successful formulation, Neos is responsible for manufacturing the licensed product for use in connection with Cornerstone's clinical trials and Cornerstone's submission of an NDA to the FDA for the licensed product. Neos also has the exclusive right to manufacture the licensed product for commercial sale following FDA approval pursuant to a separate supply agreement that the parties would enter into following FDA approval of the licensed product.

#### *Fees, Milestones and Royalties*

Under the agreement, Cornerstone is obligated to pay Neos a minimum fee of approximately \$1.8 million for its performance of the development work under the agreement, plus hourly fees related to development work performed by Neos personnel as reflected in a mutually agreed development plan or otherwise approved by Cornerstone.

In consideration for Neos's exclusive license of patent-pending Dynamic Variable Release technology and related know-how, Cornerstone is obligated to pay royalties determined as a percentage of net sales of any licensed product.

#### *Term and Termination*

The agreement expires on the earlier of March 19, 2013 or FDA approval of the NDA for the licensed product. Cornerstone may terminate the agreement with 90 days' prior written notice if Neos fails to meet any milestones or quality targets determined in the development plan and may terminate the agreement immediately if Neos's manufacturing site is revoked as a cGMP manufacturing facility by the FDA. Cornerstone also may terminate the



agreement with 60 days prior written notice if the product is unable to

achieve a suitable pharmacokinetic profile as determined by the bioavailability study in the development plan or if Cornerstone receives a not approvable letter from the FDA with respect to the licensed product.

If the NDA is approved by the FDA, Neos's license of its Dynamic Variable Release technology and related know-how to Cornerstone and Neos's exclusive manufacturing rights with respect to any licensed product will continue in full force and effect despite the expiration of the agreement generally. Additionally, Cornerstone's obligation to pay royalties with respect to any licensed product will continue until March 19, 2013 if no U.S. patent with a valid claim covering the licensed product has been issued or, if later, such date as there no longer exists a valid claim covering the licensed product under an issued U.S. patent or patent application.

#### ***Neos and Coating Place Hydrocodone Cough Suppressant Products***

In February 2008, Cornerstone entered into a development and manufacturing agreement with Neos and Coating Place, Inc., pursuant to which Cornerstone obtained an exclusive license under Neos's patent-pending Dynamic Variable Release technology and Dynamic Time Release Suspension technology and Coating Place's patent-pending drug resin complex technology to develop, manufacture and commercialize extended-release antihistamine and antitussive combination products to compete directly in the U.S. hydrocodone cough suppressant market, subject to obtaining necessary approvals from the FDA. Under the agreement, Coating Place has the exclusive right to supply Neos with the drug resin complex needed to manufacture the licensed products. Neos is responsible for formulation development related to the licensed products and has the exclusive right to manufacture the licensed products for commercial sale. Cornerstone is responsible for all regulatory activities with respect to licensed products in the United States including preparation and submission of a new drug application and, following FDA approval, is responsible for selling, marketing and distributing the licensed products. Cornerstone is obligated to use commercially reasonable efforts to develop and launch the licensed products as soon as practicable and thereafter to maximize sales of the licensed products in the United States.

#### ***Fees, Milestones and Royalties***

In consideration for its rights under the agreement, Cornerstone paid Neos and Coating Place aggregate upfront fees of \$500,000, and following product launch, Cornerstone, Neos and Coating Place will share the net profits from sales of the licensed products equally.

#### ***Product Development, Regulatory and Commercialization Expenses***

Under the agreement, Cornerstone is obligated to reimburse Neos and Coating Place for their respective costs of performing the development work related to the licensed products. Prior to product launch, Cornerstone is responsible for all expenses incurred for regulatory filings with the FDA except the parties have agreed to share equally the PDUFA fees for licensed products. Following product launch, Cornerstone's expenses of maintaining the FDA drug approval and its selling, marketing and distribution expenses will be deducted from gross profits from the sale of licensed products prior to the division of net profits among the parties.

#### ***Term and Termination***

The term of this agreement is 15 years from the date the first product is approved by the FDA, with the opportunity for one or more additional five-year successive terms, as mutually agreed by the parties.

Additionally, if Cornerstone has failed to commercially launch the first product in the United States by the fifth anniversary of the agreement, any party may immediately terminate the agreement by written notice to the other parties. Additionally, upon the failure of clinical testing with respect to Neos's proposed formulation for the first

product or Cornerstone's receipt of an FDA rejection of Cornerstone's drug approval application with respect to the first product, if Cornerstone decides not to proceed with additional work or studies, then Cornerstone has the right to immediately terminate the agreement by written notice to the other parties.

***Sovereign Supply and Marketing Agreement for Sovereign's Hyoscyamine Products***

In May 2008, Cornerstone entered into a supply and marketing agreement with Sovereign obtaining the exclusive right to market, sell and distribute in the United States three of Sovereign's generic products, each containing the API hyoscyamine. Under this agreement, Cornerstone is obligated to use commercially reasonable efforts to market, sell and distribute each of the three hyoscyamine products manufactured by Sovereign to wholesalers and distributors in the United States in return for a 50% share of the net profits realized from the sale of the products.

The initial term of the agreement expires April 30, 2011 and will be automatically renewed for successive one-year terms unless either party provides written notice of termination. Cornerstone also may immediately terminate the agreement by written notice if Sovereign undergoes a change of control as defined in the agreement or if the FDA or other regulatory authority orders the discontinuance for any reason of the commercial sale of the products. Notwithstanding the expiration or termination of the Agreement, Cornerstone may continue to sell all hyoscyamine products in its inventory until such inventory is exhausted unless commercial sale of the products has been discontinued pursuant to orders of the FDA or other regulatory authority.

***Vintage Propoxyphene/Acetaminophen Products***

In July 2004, Cornerstone entered into an asset purchase agreement, amended in March 2006, with Vintage obtaining the rights, title and interest to two propoxyphene/acetaminophen combination products: propoxyphene napsylate/acetaminophen 100mg/325mg tablet ANDA #76-743 and propoxyphene napsylate/acetaminophen 100mg/500mg tablet ANDA #76-750, which is a generic version of Darvocet® a500. Under this agreement, Cornerstone has all rights to promotion, marketing, sale, distribution and manufacturing of these two products, and is obligated to pay Vintage a royalty equal to a percent of net sales each calendar quarter.

***Pliva APAP 500 Supply and Marketing Agreement***

In September 2005, Cornerstone entered into a supply and marketing agreement with Pliva, granting Pliva the exclusive right to market Cornerstone's propoxyphene napsylate and acetaminophen 100mg/500mg product, APAP 500, in the United States and its territories. Under this agreement, Cornerstone handles the regulatory processes and Vintage supplies Pliva with the APAP 500 product. Under this agreement, Pliva is obligated to pay Cornerstone a percentage of net sales each calendar quarter through the term of the agreement.

The current term of this agreement expires December 31, 2008. Cornerstone has given notice to Pliva that at the end of the current term, it will terminate the agreement. At the end of the term, Cornerstone will commence sales and marketing of this product directly.

***Auriga EXTENDRYL Sublicense***

In January 2005, Cornerstone obtained the rights to EXTENDRYL, a family of respiratory medication products, through a sublicense agreement with Tryon Laboratories, Inc., which had acquired its rights to EXTENDRYL pursuant to a sublicense from Fleming and Company Pharmaceuticals, or Fleming. In May 2005, Cornerstone entered into a license agreement with Auriga, pursuant to which Cornerstone granted Auriga an exclusive, perpetual, worldwide sublicense to the trademark rights in EXTENDRYL and to proprietary information relating to formulations for products previously sold by Fleming under the EXTENDRYL trademark, in exchange for a royalty as a percentage of net sales of the EXTENDRYL products sold by Auriga. Effective as of September 6, 2006, Cornerstone entered into an amended and restated license agreement pursuant to which Auriga is obligated to make decreased royalty payments to Cornerstone based on a percentage of net sales. In consideration for this amended and restated agreement, Auriga issued Cornerstone 200,000 shares of Auriga common stock. Under the amended license agreement, Auriga

also is obligated to pay directly any royalty amounts that are due to Fleming under the sublicense from Fleming to Tryon Laboratories, Inc.

Pursuant to the amended license agreement, Auriga agreed, so long as the license agreement remains in effect, not to submit an NDA for a product or products containing methscopolamine. Cornerstone, however, is free to submit such an NDA. Cornerstone agreed that in the event that it obtained approval from the FDA of a Section 505(b)(2) NDA to manufacture or sell a product containing methscopolamine that Auriga would be automatically licensed under the license agreement to sell its EXTENDRYL products, in each case, as formulated with methscopolamine on the date of the license agreement and consistent with the FDA approval of the Section 505(b)(2) NDA. Pursuant to the amended license agreement, Auriga and Cornerstone also agreed not to manufacture generic versions of each other's products until the earlier of an assignment of the license agreement by either party or a transaction that results in a change in beneficial ownership of at least 50% of the voting shares of either party.

## **Competition**

The pharmaceutical industry, including the respiratory market in which Cornerstone principally competes, is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Cornerstone faces potential competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Cornerstone's current products, and any product candidates that it successfully develops and commercializes will, compete with existing therapies and new therapies that may become available in the future.

Many of Cornerstone's competitors may have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than Cornerstone does. These competitors also compete with Cornerstone in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, Cornerstone's programs or advantageous to its business. In many cases, products that compete with Cornerstone's currently marketed products and product candidates have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Cornerstone's ability to remain competitive in the marketplace is also impacted by its ability to compete successfully with other specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. These established companies may have a competitive advantage over Cornerstone due to their size and financial resources.

The key competitive factors affecting the success of all of Cornerstone's products and product candidates, if approved, are and are likely to continue to be efficacy, safety, convenience, price, the availability of patent protection or regulatory marketing exclusivity, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Cornerstone's commercial opportunity could be reduced or eliminated if its competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are more convenient or are less expensive than any products that Cornerstone may develop. Cornerstone's competitors also may obtain FDA or other regulatory approval for their products more rapidly than Cornerstone may obtain approval for its products. In addition, Cornerstone's ability to compete may be affected because in some cases insurers or other third-party payors seek to encourage the use of generic products, which may have the effect of making branded products less attractive, from a cost perspective, to buyers.

## ***Marketed Products***

Cornerstone's currently marketed products face significant competition from a wide range of branded and generic products for the same therapeutic indications. Upon loss of regulatory marketing exclusivity or patent protection or as a result of design-around strategies that allow for generic product introduction prior to the expiration of key product patents, Cornerstone is potentially subject to competition from generic versions of its

branded products. Generics are typically priced at lower levels than branded products and may substantially erode prescription demand and sales of Cornerstone's branded products. The specific competitive conditions affecting SPECTRACEF and ALLERX are more fully discussed in the sections entitled "Marketed Products" beginning on page 168 of this proxy statement/prospectus.

### ***Product Candidates***

Given that Cornerstone is developing product candidates based on currently marketed drug compounds, some or all of the products in Cornerstone's product pipeline, if approved, may face competition from generic and branded formulations of these existing drugs. Cornerstone's ability to successfully market and sell the products in its pipeline will depend on the extent to which its newly formulated product candidates have the benefit of patent protection or some other form of regulatory marketing exclusivity or are meaningfully differentiated from these existing drugs or new competitive formulations of these drugs offered by third parties. In addition, Cornerstone's product candidates, if approved, will compete with other branded and generic drugs approved for the same therapeutic indications, approved drugs used off label for such indications and novel drugs in clinical development. The competitive conditions affecting the products in Cornerstone's product pipeline is more fully discussed in the section entitled "Product Development Pipeline" beginning on page 175 of this proxy statement/prospectus.

### **Regulatory Matters**

The research, testing, manufacture and marketing of drug and biologic products are extensively regulated in the United States and abroad. In the United States, drugs and biologics are subject to rigorous regulation by the FDA. The FDCA and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, packaging, labeling, advertising and promotion, sampling and distribution of pharmaceutical and biologic products. Failure to comply with applicable regulatory requirements may subject Cornerstone to a variety of administrative or judicially imposed sanctions, including the FDA's refusal to accept new applications or to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

### ***United States Approval Process for New Drug Applications***

Before marketing a new drug product in the United States, the product sponsor must first demonstrate that the product is safe, effective and properly manufactured, and must obtain FDA approval in the form of an approved NDA, sNDA or ANDA. As a matter of FDA enforcement policy, limited categories of drugs that have historically been marketed without such approval also may remain on the market subject to the risk that the FDA may at any time require the product sponsors to obtain approval for the products or remove them from the market. In seeking FDA approval for its product candidates, Cornerstone intends to follow the development and approval pathway permitted under the FDCA that it believes will maximize the commercial opportunities for its product candidates.

Satisfaction of FDA approval requirements typically takes a minimum of several years, and the actual time required may be substantially longer depending upon the type of approval required, the complexity of the product, the target disease or the nature and extent of required clinical trials or other data requirements. Compliance with FDA approval requirements will require substantial investments of time, money and corporate resources and may significantly delay or even prevent Cornerstone from marketing potential products. Success in early stage clinical trials does not necessarily assure success in later stage clinical trials. Data obtained from clinical trials are not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in marketing or sales restrictions on the product or even complete withdrawal of the product from the market. Line



extensions or other significant changes to an approved product (e.g., adding a new dosage strength) also require submission and prior FDA approval of a supplemental application including additional clinical or other data required to demonstrate the safety and efficacy of the changed product.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the development, approval, manufacturing and marketing of drug products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect Cornerstone's business and its products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

#### *New Drug Application*

The steps ordinarily required before a new pharmaceutical product may be marketed in the United States include the conduct of preclinical laboratory tests, animal tests and formulation studies; submission to the FDA of an application for IND, which must become effective prior to commencement of human clinical testing; the conduct of adequate and well-controlled clinical trials in accordance with good clinical practices to establish that the product is safe and effective for the indication for which FDA approval is sought; the preparation and submission of the NDA; satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and FDA review and approval of the marketing application.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of compounds for testing must comply with federal regulations and requirements. The results of preclinical testing are submitted to the FDA as part of an IND during the IND stage of development and as part of the NDA.

An IND must become effective prior to the commencement of clinical testing of a drug in humans. An IND will automatically become effective 30 days after receipt by the FDA if the FDA has not commented on or questioned the application during this 30-day waiting period. If the FDA has comments or questions, these may need to be resolved to the satisfaction of the FDA prior to commencement of clinical trials. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. The IND process can result in substantial delay and expense.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations and requirements, under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the safety and effectiveness criteria to be evaluated. Each protocol for an unapproved drug involving testing human subjects in the United States must be submitted to the FDA as part of the IND. The trial protocol and informed consent information for subjects in clinical trials must be submitted to institutional review boards for approval.

Clinical trials to support new drug product applications for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase I, the initial introduction of the product candidate into healthy human subjects or patients, the product is tested to assess metabolism; pharmacokinetics; safety, including side effects associated with increasing doses; and, at times, pharmacological actions. Phase II usually involves trials in a limited patient population to determine dosage tolerance and optimum dosage, identify possible adverse effects and safety risks and provide preliminary support for the efficacy of the product in the indication being studied.

If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to evaluate further clinical efficacy and to test further for safety within an expanded patient population, typically at geographically dispersed clinical trial sites. Phase I, Phase II or Phase III testing of any

product candidates may not be completed successfully within any specified time period, if at all. Furthermore, the FDA, an institutional review board or Cornerstone may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

After successful completion of the required clinical testing for a drug, generally an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include, among other things, the results of all clinical and preclinical safety testing and a compilation of the data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of NDAs are additionally subject to substantial application user fees, currently exceeding \$1.1 million, the fee for submission of supplemental applications exceeds \$580,000 and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently exceeding \$65,000 per product and up to \$392,000 per establishment. These fees are typically increased annually.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended and reauthorized by the FDAAA, an NDA or supplement to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDAAA also authorizes the FDA to require sponsors of currently marketed drugs to conduct pediatric studies if the drug serves a substantial number of pediatric patients and adequate pediatric labeling could benefit such patients, the drug would provide a meaningful therapeutic benefit for pediatric patients or the absence of pediatric labeling could pose a risk to pediatric patients. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the drug for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The review process is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA normally also will conduct a pre-approval inspection to ensure the manufacturing facility, methods and controls are adequate to preserve the drug's identity, strength, quality, purity and stability and are in compliance with regulations governing current good manufacturing practices. In addition, the FDA usually conducts audits of the clinical trials for NDAs and efficacy supplements to ensure that the data submitted reflects the data generated by the clinical sites.

If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA and issue a not approvable letter. The not approvable letter outlines the deficiencies in the submission and often requires additional testing or information in order for the FDA to reconsider the application. Even after submitting this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of an NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

If the FDA's evaluations are favorable, the FDA may issue an approval letter or, in some cases, an approvable letter followed by an approval letter. An approvable letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require post-approval trials and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions and restricted distribution, which can materially impact the potential market and profitability of the drug.



### *Supplemental New Drug Application*

Once an NDA is in effect, the drug sponsor must notify the FDA of any change in an approved product beyond variations already allowed in the marketing approval. Significant changes generally require prior approval of an sNDA, which may require additional clinical trials or other data required to demonstrate that the product as modified remains safe and effective. For example, Cornerstone has submitted an sNDA with respect to SPECTRACEF 400 mg since this product represents a change in strength from the 200 mg version of SPECTRACEF. Other modifications which would require sNDA approval include substantive changes in labeling, the addition of one or more new indications for use, a new dosage form (e.g., introduction of a new extended-release formulation), and significant manufacturing changes including a new manufacturing site. Such supplements, referred to as Prior Approval Supplements, must contain information to demonstrate that the modified product will remain safe, effective, and consistently manufactured. FDA does not require duplication of previously-submitted data that remain applicable to proposed NDA modification.

According to the FDA's guidelines and PDUFA agreements, the FDA should review sNDAs within six months of submission. Once an sNDA is submitted to the FDA the company receives from the FDA a filing date, which is the date the FDA received and processed the filing for documentation. This notification from the FDA to the company usually also includes an action date which is the date the FDA sets to indicate approval or non-approval of the submission. An applicant may ask the FDA to expedite its review for public health reasons, such as a drug shortage.

The process of obtaining FDA approval for an sNDA may be expensive and time-consuming, and if not approved, the product will not be allowed to be marketed as modified.

### *Abbreviated New Drug Application*

The ANDA route of approval provides for marketing of a generic drug product that has the same active pharmaceutical ingredients in the same strengths and dosage form as an NDA-approved reference listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug products, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

When a drug product is approved through an NDA, its sponsor must list with the FDA each patent with claims that cover the product or an approved use of the product. Upon NDA approval, the drug product and associated patent information are published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited as the reference listed drug by subsequent ANDA applicants. The ANDA applicant must supply information demonstrating its generic product meets the sameness and bioequivalence requirements described above, as well as detailed manufacturing information. Additionally, ANDA applicants must certify to the FDA with respect to each patent listed for the reference listed product in the Orange Book. Specifically, the applicant must certify that:

the required patent information has not been filed;

the listed patent has expired;

the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or

the listed patent is invalid or unenforceable or will not be infringed by the manufacture, use or sale of the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the

referenced product have expired. If there are no listed patents, or all patents have expired, ANDA approval will not be delayed.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders with a detailed statement of the factual and legal basis for the applicant's belief that the patents are invalid, unenforceable or not infringed once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV notice automatically prevents the FDA from approving the ANDA for up to 30 months from the date of receipt of notice by the patent holder. The Hatch-Waxman Act explicitly encourages generic challenges to listed patents by providing for a 180-day period of generic product exclusivity for the first generic applicant to challenge a listed patent for an NDA-approved drug. Thus, many if not most successful new drug products are subject to generic applications and patent challenges prior to the expiration of all listed patents.

#### *Section 505(b)(2) New Drug Applications*

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an approved product, or on published literature, in support of its application.

Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products, or for the initial approval of drugs previously marketed without NDAs/ANDAs under the Prescription Drug Wrap-Up program discussed below. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings with respect to particular preclinical studies or clinical trials conducted for an approved product, or upon published clinical and scientific data. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is subject to existing exclusivity for the referenced product and is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired; until any nonpatent exclusivity, such as exclusivity for obtaining approval of a new chemical entity listed in the Orange Book for the referenced product, has expired; and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months or a decision or settlement in the infringement case finding the patents to be invalid, unenforceable or not infringed.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that Cornerstone submits.

#### *Prescription Drug Wrap-Up*

The FDCA, enacted in 1938, was the first statute requiring premarket approval of drugs by the FDA. These approvals, however, focused exclusively on safety data. In 1962, Congress amended the FDCA to require that sponsors



demonstrate that new drugs are effective, as well as safe, in order to receive FDA approval. These amendments also required the FDA to conduct a retrospective evaluation of the effectiveness of the drug products that the FDA approved between 1938 and 1962 on the basis of safety alone. The agency contracted

with the National Academy of Science/National Research Council, or the NAS/NRC, to make an initial evaluation of the effectiveness of many drug products. The FDA's administrative implementation of the NAS/NRC reports was the DESI.

Drugs that were not subject to applications approved between 1938 and 1962 were not subject to DESI review. For a period of time, the FDA permitted these drugs to remain on the market without approval. In 1984, however, spurred by serious adverse reactions to one of these products, Congress urged the FDA to expand the new drug requirements to include all marketed unapproved prescription drugs. The FDA created a program, known as the Prescription Drug Wrap-Up, to address these remaining unapproved drugs. Most of these drugs contain active pharmaceutical ingredients that were first marketed prior to the enactment of the FDCA in 1938. Cornerstone believes that several of its marketed pharmaceutical products fall within this category.

The FDA asserts that all drugs subject to the Prescription Drug Wrap-Up are on the market illegally and are subject to FDA enforcement action at any time. There are several narrow exceptions. For example, both the original statutory language of the FDCA and the 1962 amendments include grandfather provisions exempting certain drugs from the new drug requirements. The 1938 clause exempts drugs that were on market prior to the passage of the FDCA in 1938 and that contain the same representations concerning the conditions of use as they did prior to passage of the Act. The 1962 amendments exempt, in certain circumstances, drugs that have the same composition and labeling as they had prior to the passage of the 1962 amendments. The FDA and the courts have interpreted these two exceptions very narrowly. As to drugs marketed over the counter, the FDA exempts through regulation products that have been determined to be generally recognized as safe and effective and have been used to a material extent and for a material time.

The FDA has adopted a risk-based enforcement policy that prioritizes enforcement of the new drug approval requirement for unapproved drugs that pose a safety threat, lack evidence of effectiveness, prevent patients from pursuing effective therapies or are marketed fraudulently. In addition, the FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug approval requirement. Once the FDA issues an approved NDA for one of the drug products at issue or completes the efficacy review for that drug product, it may require other manufacturers to also file an NDA or an ANDA for that same drug in order to continue marketing it in the United States. While the FDA generally provides sponsors a one-year grace period, it is not statutorily required to do so.

### ***Post-Approval Compliance Requirements and Changes to Approved Products***

Whatever route of approval is used to gain FDA marketing approval, all marketed drug products are subject to certain post-approval requirements, including requirements for adverse event reporting and a range of periodic reporting and recordkeeping requirements. Drug manufacturers also must comply with the FDA's cGMP regulations, which govern all phases of the drug production process, and manufacturing facilities are subject to periodic FDA inspection for cGMP compliance. In addition, the FDA strictly regulates the promotional claims that may be made about prescription drug products and biologics. In particular, the FDA requires substantiation of any claims of superiority of one product over another, including that such claims be proven by adequate and well-controlled head-to-head clinical trials. To the extent that market acceptance of Cornerstone's products may depend on their superiority over existing therapies, any restriction on Cornerstone's ability to advertise or otherwise promote claims of superiority, or requirements to conduct additional expensive clinical trials to provide proof of such claims, could negatively affect the sales of Cornerstone's products or its costs. Violation of any FDA requirements could result in enforcement actions, such as withdrawal of approval, product recalls, product seizures, injunctions, total or partial suspension of production or distribution, fines, consent decrees, civil penalties and criminal prosecutions, which could have a material adverse effect on Cornerstone's business.

Cornerstone must also notify the FDA of any change in an approved product beyond variations already allowed in the marketing approval. Once an NDA is in effect (including a 505(b)(2) NDA), significant changes such as a change in labeling, the addition of one or more new indications for use, a new dosage or strength of a drug or a change in the way Cornerstone manufactures a drug, generally require prior approval of an sNDA,

which may require additional clinical trials or other data required to demonstrate that the product as modified remains safe and effective. Any modification of an ANDA-approved product that would cause the product to no longer be identical to its listed reference product requires prior approval in the form of a new NDA or 505(b)(2) NDA. Approvals of labeling or manufacturing changes may be expensive and time-consuming, and if not approved, the product will not be allowed to be marketed as modified.

### ***Marketing Exclusivity and Patent Term Restoration***

Under the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same API. The Hatch-Waxman Act prohibits the submission of an ANDA or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusivity period. However, submission of an ANDA or Section 505(b)(2) NDA containing a Paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Although protection under the Hatch-Waxman Act will not prevent the submission or approval of another full NDA, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosage forms, routes of administration, or strengths of an existing drug, or for a new use, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application. Cornerstone currently expects to seek three-year marketing exclusivity for SPECTRACEF Once Daily. This exclusivity would not prevent the approval of another application if the applicant has conducted its own adequate and well controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of a generic product that did not incorporate the exclusivity protected changes of the approved drug product.

### ***Pediatric Exclusivity***

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patent term. This six-month exclusivity may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued Written Request for such a study. Cornerstone plans to work with the FDA to determine the need for pediatric studies for its product candidates and may consider attempting to obtain pediatric exclusivity for some of its product candidates.

### ***Foreign Regulation***

Approval of a product by comparable regulatory authorities may be necessary in foreign countries prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. The approval procedure varies among countries and can involve requirements for additional testing. The time required may differ from that required for FDA approval. Although there are some procedures for unified filings for some European countries, such as the sponsorship of the country which first granted marketing approval, in general each country has its own procedures and requirements, many of which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from foreign regulatory authorities after the relevant applications are filed.

### ***Regulation of Controlled Substances***

Cornerstone sells products that are controlled substances as defined in the Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, labeling, packaging, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing an initial registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, including distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics and other designated substances. Reports must also be made for thefts or significant losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, so-called DEA Form 222, with copies provided to the DEA. Because hydrocodone and propoxyphene are Schedule II controlled substances, they are subject to the DEA's production and procurement quota scheme. The DEA establishes annually aggregate quotas for how much hydrocodone and propoxyphene may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amounts of these substances that the DEA allows to be produced in the United States each year are allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. Cornerstone and its contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including propoxyphene for use in BALACET 325 and APAP 500, and hydrocodone for use in the Hydrocodone Cough Suppressants. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Cornerstone's, or its contract manufacturers', quota of an API may not be sufficient to meet commercial demand or complete clinical trials. Any delay or refusal by the DEA in establishing Cornerstone's, or its contract manufacturers', quota for controlled substances could delay or stop Cornerstone's clinical trials or product launches, which could have a material adverse effect on Cornerstone's business, financial position and results of operations.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on Cornerstone's business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Individual states also regulate controlled substances, and Cornerstone and its contract manufacturers will be subject to state regulation on distribution of these products.

### *Hazardous Materials*

Cornerstone relies on third parties to assist it in developing and manufacturing all of its products and does not directly handle, store or transport hazardous materials or waste products. The development and manufacturing activities performed by third parties at Cornerstone's request may involve the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. Cornerstone relies on its third

parties to comply with all applicable federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. Cornerstone does not expect the cost of complying with these laws and regulations to be material to it.

### **Pharmaceutical Pricing and Reimbursement**

Cornerstone's ability to commercialize its products successfully depends in significant part on the availability of adequate coverage and reimbursement from third-party payors, including governmental payors such as the Medicare and Medicaid programs, MCOs, and private health insurers. Third-party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. Cornerstone may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of its products, in addition to the costs required to obtain FDA approvals. Even with these studies, Cornerstone's products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may decide not to provide coverage and reimbursement for its product candidates, in whole or in part. If third-party payors approve coverage and reimbursement, the resulting payment rates may not be sufficient for Cornerstone to sell its products at a profit.

Political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental changes. There have been, and Cornerstone expects there will continue to be, legislative and regulatory proposals to change the health care system in ways that could significantly affect Cornerstone's business. Cornerstone anticipates that the United States Congress, state legislatures and the private sector will continue to consider and may adopt health care policies intended to curb rising health care costs. These cost containment measures could include, for example:

- controls on government funded reimbursement for drugs;

- controls on payments to health care providers that affect demand for drug products;

- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;

- weakening of restrictions on imports of drugs; and

- expansion of use of managed care systems in which health care providers contract to provide comprehensive health care for a fixed cost per person.

Under the Medicare Part D prescription drug benefit, which took effect in January 2006, Medicare beneficiaries can obtain prescription drug coverage from private plans that are permitted to limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class. Under this program, Cornerstone's products may be excluded from formularies and may be subject to significant price competition that depresses the prices it is able to charge. Cornerstone believes that it is likely that private managed care plans will follow Medicare coverage and reimbursement policies.

Outpatient pharmaceuticals sold to state administered Medicaid programs are subject to the national Medicaid drug rebate program. In order to have their drugs covered by state Medicaid programs, pharmaceutical companies must enter into an agreement under which they agree to pay a rebate to the states which is determined on the basis of a specified percentage of the average manufacturer price or the difference between the average manufacturer price and the best price. Pharmaceutical companies must also enter into a similar agreement with the U.S. Department of Veterans Affairs to have their drugs covered by state Medicaid programs, and some states may impose supplemental



rebate agreements. Cornerstone is a party to these types of pricing agreements with respect to its currently marketed products.

Cornerstone may also face competition for its products from lower-priced products from foreign countries that have placed price controls on pharmaceutical products. Proposed federal legislative changes may expand consumers' ability to import lower-priced versions of competing products from Canada and other countries. In August 2007, the United States House of Representatives passed a measure that would permit more imports of prescription drugs, but the United States Senate has not yet approved it. If this proposal or similar proposals become law, Cornerstone's products may be subjected to increased price competition from lower priced

imported drugs. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, Cornerstone expects other states and local governments to launch importation efforts. The importation of foreign products that compete with Cornerstone's own products could negatively impact its business and prospects.

Cornerstone is unable to predict what additional legislation, regulations or policies, if any, relating to the health care industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on its business. Any cost containment measures, including those listed above, or other health care system reforms that are adopted could impair Cornerstone's ability to set prices that cover its costs, constrain its ability to generate revenue from government funded or private third party payors, limit the revenue and profitability of its potential customers, suppliers and collaborators and impede its access to capital needed to operate and grow. Any of these circumstances could significantly limit Cornerstone's ability to operate profitably.

### **Fraud and Abuse Regulation**

A number of federal and state laws and related regulations, loosely referred to as fraud and abuse laws, are used to prosecute health care providers, suppliers, physicians and others that fraudulently or wrongfully obtain reimbursement for health care products or services from government health programs, such as Medicare and Medicaid. These laws apply broadly and may constrain Cornerstone's business and the financial arrangements through which it markets, sells and distributes its products. These laws and regulations include:

*Federal Anti-Kickback Law.* The anti-kickback law contained in the federal Social Security Act is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay, or to solicit or receive, direct or indirect remuneration, in order to induce business reimbursed under a federal health care program, including Medicare and Medicaid. The term "remuneration" was intended to be and has been interpreted broadly and includes both direct and indirect compensation. Both the party offering and paying remuneration and the recipient may be found to have violated the statute. Courts have interpreted the anti-kickback law to cover any arrangement where one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals, regardless of whether there are also legitimate purposes for the arrangement. There are narrow exclusions authorizing arrangements that strictly comply with specified safe harbor criteria, but many legitimate transactions fall outside of the scope of any safe harbor standard, although that does not necessarily mean the arrangement will be subject to penalties under the anti-kickback statute. Penalties for federal anti-kickback violations are severe, including up to five years imprisonment, individual and corporate criminal fines, exclusion from participation in federal health care programs and civil monetary penalties in the form of treble damages plus \$50,000 for each violation of the statute. It is possible that government regulators may find that Cornerstone's arrangements do not comply with this broad and often ambiguous law, to the extent it is determined that the statute is implicated by any of Cornerstone's arrangements.

*Stark Law.* The federal Statute on Limitations of Certain Physician Referrals, commonly referred to as the Stark Law, prohibits physician referrals for designated health services to entities in which the referring physician or an immediate family member has a financial interest, either through an ownership or investment interest or a compensation arrangement, unless the arrangement falls within a specific, narrow exception. Manufacturers and suppliers are prohibited from submitting and receiving federal health care program reimbursement for products or services sold as a result of prohibited referrals. Violations of the statute can result in civil monetary penalties and exclusion from federal health care programs. It is possible that Cornerstone's physician customers may have certain financial interests prohibited by the Stark Law.

*State Laws.* Various states have enacted laws and regulations comparable to the federal fraud and abuse laws and regulations. These state laws may apply to items or services reimbursed by any third-party payor, including private, commercial insurers and other payors. Moreover, these laws vary significantly from state to state and, in some cases, are broader than the federal laws. This increases the

costs of compliance and the risk that the same arrangements may be subject to different compliance standards in different states.

### **Corporate Organization**

Cornerstone is comprised of Cornerstone BioPharma Holdings, Inc., or Holdings, and its subsidiaries. Holdings was incorporated in Delaware in 2005. Cornerstone's operations are performed primarily by a subsidiary of Holdings, Cornerstone BioPharma, Inc., which was incorporated in Nevada in 2004 as Cornerstone Pharmaceuticals, Inc. Holdings acquired Cornerstone BioPharma, Inc. in 2005 from Cornerstone Biopharma Holdings, Ltd., a company under common control with Holdings.

### **Employees**

As of June 30, 2008, Cornerstone had 79 full-time and six part-time employees, 68 of whom were engaged in marketing and sales; four of whom were engaged in research, development and regulatory affairs; and 13 of whom were engaged in management, administration and finance. None of Cornerstone's employees are represented by a labor union or covered by a collective bargaining agreement, and Cornerstone has not experienced any work stoppages. Cornerstone believes that relations with its employees are good.

### **Properties**

Cornerstone presently leases its corporate headquarters, which occupies approximately 7,800 square feet of office space and is located in the Regency Park office complex, in Cary, North Carolina. The lease has five-year term expiring in October 2009. Cornerstone paid an annual rent under this lease of approximately \$157,000 during 2007. Cornerstone is currently in negotiations with the landlord under this lease concerning the terms and conditions that would apply to an early termination of the lease in connection with the relocation of Cornerstone's corporate headquarters as described below.

In May 2008, Cornerstone entered into a lease agreement for a new corporate headquarters, which will occupy approximately 14,900 square feet of office space and is located in the Crescent Lakeside office complex, in Cary, North Carolina. The lease has an initial term that commences in December 2008 and expires in March 2016. Initial annual base rent under the lease is approximately \$350,000 with annual rent increases of approximately three percent. Cornerstone also has an option to renew the lease for an additional five-year term through March 2021.

### **Legal Proceedings**

In November 2006, Cornerstone was named as a defendant in an action filed in New York County, New York by Adams captioned *Adams Respiratory Therapeutics, Inc. (f/k/a Adams Laboratories, Inc.) v. Cornerstone BioPharma, Inc. and Carolina Pharmaceuticals, Inc.*, Supreme Court of the State of New York, New York County, Index No. 603969/2006. The complaint alleged breach of contract concerning a settlement agreement between Cornerstone and Adams dated January 14, 2005. The complaint also alleged claims concerning the settlement agreement for account stated, fraudulent misrepresentation and negligent misrepresentation. The complaint sought damages ranging from approximately \$910,000 to an unspecified amount in excess of \$2.5 million. Cornerstone filed an answer to the complaint in which it denied the material allegations of the Complaint and asserted counterclaims against Adams for breach of contract concerning the settlement agreement. Cornerstone's counterclaims sought damages in excess of \$2 million. Following mediation in March 2008, the parties reached an agreement to settle all matters between them, which resulted in the parties' execution of a new settlement agreement in May 2008. The litigation was dismissed, subject to the filing of a motion by Adams to reinstate the litigation on or before October 15, 2008 in the event of a default by Cornerstone and Carolina Pharmaceuticals under the new settlement agreement. Under the terms of the new

settlement agreement, Cornerstone and Carolina Pharmaceuticals agreed to pay Reckitt Benckiser, Inc., the parent of Adams, \$1.5 million, of which \$1.0 million had been paid by the end of June 2008 and the remaining \$500,000 is due and payable by the end of September 2008.

Prior to March 2008, Cornerstone used a different formulation for ALLERX 10 Dose Pack and ALLERX 30 Dose Pack that Cornerstone believes was protected under claims in the U.S. patent number 6,270,796, or the '796 Patent. Cornerstone and J-Med Pharmaceuticals, Inc., or J-Med, the licensor of the '796 Patent, have asserted infringements of the '796 Patent in litigation with each of Everton Pharmaceuticals, LLC, Breckenridge Pharmaceuticals, Inc., and Vision, and manufacturers and related parties of each, alleging that those parties had infringed the '796 Patent by making, using, selling, offering for sale or importing into the United States pharmaceutical products intended as generic equivalents to the former formulation of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack protected under claims in the '796 Patent. Everton and Breckenridge entered into settlement agreements in January 2007 and July 2007, respectively, and agreed to cease selling the infringing products. In October 2007, Cornerstone and J-Med filed an action in the U.S. District Court for the Eastern District of North Carolina against Vision and Nexgen Pharma, Inc. captioned *Cornerstone BioPharma, Inc. and J-Med Pharmaceuticals, Inc. v. Vision Pharma, LLC and Nexgen Pharma, Inc.*, No. 5:07-CV-00389-F. In this action, Cornerstone and J-Med alleged that the product known as VisRx infringes the '796 Patent. On November 19, 2007, Cornerstone and J-Med filed an amended complaint in which they asserted claims against Vision's principals, Sander Busman, Thomas DeStefano and Michael McAloose. On November 30, 2007, defendants moved to stay the litigation pending the re-examination of the '796 Patent. The Court granted defendants' motion and stayed the litigation pending the re-examination of the '796 Patent on February 15, 2008. Separately, the U.S. Patent and Trademark Office ordered a re-examination of the '796 Patent as a result of a third-party request for ex parte re-examination.

In proceedings before a re-examination examiner in the U.S. Patent and Trademark Office, the examiner rejected claims of the '796 Patent as failing to satisfy novelty and non-obviousness criteria for U.S. patent claims. J-Med appealed to the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences, or Board of Patent Appeals, on June 13, 2008, seeking reversal of the examiner's rejections. On the same date, J-Med filed additional documents with the U.S. Patent and Trademark Office for review by the examiner. If the examiner does not reverse his prior rejections, then the Board of Patent Appeals will act on the case and can take various actions, including affirming or reversing the examiner's rejections in whole or part, or introducing new grounds of rejection of the '796 Patent claims. If the Board of Patent Appeals thereafter affirms the examiner's rejections, J-Med can take various further actions, including requesting reconsideration by the Board of Patent Appeals, filing a further appeal to the U.S. Court of Appeals for the Federal Circuit or instituting a reissue of the '796 Patent with narrowed claims. The further proceedings involving the '796 Patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the '796 Patent.

On June 13, 2008, counsel for Vision filed in the U.S. Patent and Trademark Office a request for re-examination of certain claims under the '372 Patent, which Cornerstone believes covers ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30. Counsel for Cornerstone reviewed the request for re-examination and the patents and publications cited by counsel for Vision, and Cornerstone's counsel have concluded that valid arguments exist for distinguishing the claims of the '372 Patent over the references cited in the request for re-examination. The U.S. Patent and Trademark Office has three months within which to determine whether a substantial new question of patentability is raised by the patents and publications cited by Vision. If the U.S. Patent and Trademark Office concludes that no substantial new question of patentability is present, then its determination is final and non-appealable. If the U.S. Patent and Trademark Office concludes that a substantial new question of patentability is presented, the '372 Patent will be reexamined. Cornerstone thereupon will have opportunity in coordination with the patent owner, Pharmaceutical Innovations, to present substantive arguments supporting the patentability of the claims issued in the '372 Patent. If a re-examination examiner in the U.S. Patent and Trademark Office rejected claims of the '372 Patent, Pharmaceutical Innovations could appeal to the Board of Patent Appeals seeking reversal of the examiner's rejections. If Pharmaceutical Innovations did not receive relief from the Board of Patent Appeals, Pharmaceutical Innovations could file a further appeal to the U.S. Court of Appeals for the Federal Circuit or could institute a reissue of the '372 Patent with narrowed claims. The further proceedings involving the '372 Patent therefore may be lengthy in duration, and may result in invalidation of some or all of the claims of the '372

Patent.

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In February 2008, Cornerstone filed a Notice of Opposition before the Trademark Trial and Appeal Board in relation to Application No. 77/226,994 filed in the U.S. Patent and Trademark Office by Vision, seeking registration of the mark VisRx. The opposition proceeding is captioned *Cornerstone BioPharma, Inc. v. Vision Pharma, LLC*, Opposition No. 91182604. In April 2008, Vision filed an Answer to Notice of Opposition and Counterclaims in which it requested cancellation of U.S. Registrations No. 3,384,232 and 2,448,112 for the mark ALLERX owned by Cornerstone. Vision did not request monetary relief. Cornerstone responded to the counterclaims by Vision on May 16, 2008. Cornerstone intends to defend its interests vigorously against the counterclaims asserted by Vision.

On May 15, 2008, the U.S. Patent and Trademark Office sent written notice to Cornerstone that a cancellation proceeding had been initiated by Bausch & Lomb Incorporated, or Bausch & Lomb, against the ALLERX trademark registration. The petition to cancel filed in this proceeding alleges that the ALLERX registration dilutes the distinctive quality of Bausch & Lomb's Alex<sup>®</sup> trademark and that Bausch & Lomb is likely to be damaged by the ALLERX registration. Cornerstone is currently engaged in settlement discussions with Bausch & Lomb concerning a refinement of the product description in the ALLERX trademark registration to distinguish it from the product marketed by Bausch & Lomb under the Alex trademark. Cornerstone responded to the Trademark Trial and Appeal Board on June 24, 2008, opposing the claims in the Bausch & Lomb cancellation petition, while concurrently continuing to seek settlement of the cancellation proceeding on favorable terms. Cornerstone could take any of numerous courses of action, including continuing to oppose the claims of Bausch & Lomb, undertaking action to cancel Bausch & Lomb's registration of its Alex<sup>®</sup> trademark or entering into discovery. A final decision by the Trademark Trial and Appeal Board could take several years.



## **CRITICAL THERAPEUTICS MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

### **Management's Discussion and Analysis of Financial Condition and Results of Operations**

You should read the following discussion and analysis of financial condition and results of operations together with the Selected Historical Consolidated Financial Data of Critical Therapeutics section of this proxy statement/prospectus and Critical Therapeutics consolidated financial statements and the related notes included in this proxy statement/prospectus. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Critical Therapeutics actual results could differ materially from those anticipated by the forward-looking statements due to important factors including, but not limited to, those set forth in the Risks Related to Critical Therapeutics section of this proxy statement/prospectus.

#### **Overview**

Critical Therapeutics is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory diseases, as well as other inflammatory diseases linked to the body's inflammatory response. Critical Therapeutics two marketed products are ZYFLO CR, which the FDA approved in May 2007, and ZYFLO, which the FDA approved in 1996, for the prevention and chronic treatment of asthma in adults and children 12 years of age or older. Critical Therapeutics licensed from Abbott exclusive worldwide rights to ZYFLO CR, ZYFLO and other formulations of zileuton for multiple diseases and conditions.

Critical Therapeutics began selling ZYFLO CR in the United States in September 2007 and began selling ZYFLO in the United States in October 2005. In February 2008, Critical Therapeutics stopped the manufacture and supply of ZYFLO to the market. In March 2008, Critical Therapeutics began to experience supply chain issues with batches of ZYFLO CR that cannot be released into Critical Therapeutics commercial supply chain because they did not meet its product release specifications. Critical Therapeutics expects to resume distribution of ZYFLO in August 2008 to help manage the potential impact to patients of supply chain issues for ZYFLO CR.

In addition, Critical Therapeutics is developing zileuton injection initially for use in emergency room or urgent care centers for patients who suffer acute exacerbations of asthma. In June 2008, Critical Therapeutics announced results from its Phase II clinical trial with zileuton injection in patients with chronic, stable asthma. Critical Therapeutics intends to initiate a process to seek to enter into a collaboration agreement for the future clinical development and commercialization of zileuton injection.

Critical Therapeutics is also developing other product candidates directed towards reducing the potent inflammatory response that it believes is associated with the pathology, morbidity and, in some cases, mortality in many acute and chronic diseases. The inflammatory response occurs following stimuli such as infection or trauma. Critical Therapeutics product candidates target the production and release into the bloodstream of proteins called cytokines that play a fundamental role in the body's inflammatory response.

Critical Therapeutics has been conducting preclinical work in its alpha-7 program. Critical Therapeutics believes the successful development of a small molecule product candidate targeting the alpha-7 receptor could lead to a novel treatment for severe acute inflammatory disease, as well as an oral anti-cytokine therapy that could be directed at chronic inflammatory diseases such as asthma and rheumatoid arthritis. Based on preclinical studies, Critical Therapeutics selected lead and backup molecules for evaluation in GLP toxicology studies. Provided the data are supportive and sufficient resources are available, Critical Therapeutics believes that an IND could be filed in 2009. In

addition, Critical Therapeutics plans to seek collaborations with other pharmaceutical companies for its alpha-7 program to develop and commercialize possible product candidates in multiple development opportunities that may exist within this program prior to the initiation of human clinical trials. Critical Therapeutics licensed to IMI patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. This license agreement specifically excludes from the licensed field pharmacological modulation of the alpha-7 receptor.

Critical Therapeutics has been collaborating with MedImmune on the development of monoclonal antibodies directed toward an HMGB1 which Critical Therapeutics believes may be an important target for the development of products to treat diseases mediated by the body's inflammatory response. In addition, Critical Therapeutics has been collaborating with Beckman Coulter on the development of a diagnostic directed toward measuring HMGB1 in the bloodstream.

Until the closing of the proposed merger with Cornerstone, Critical Therapeutics expects to continue its commercial and development activities in accordance with its existing business strategy with an increased focus on managing its cash position. The description of Critical Therapeutics' business set forth in this proxy statement/prospectus does not reflect any changes to Critical Therapeutics' business that may occur if it consummates the proposed merger with Cornerstone. For instance, the combined company's clinical and preclinical pipeline will include a number of product candidates. The combined company is expected to implement a strategic review of its product development pipeline. Following the strategic review, the combined company may seek to maximize the value of any non-core programs through out-licensing, divestiture or spin-off transactions.

On April 21, 2008, Critical Therapeutics received notification that for the prior 30 consecutive business days the bid price of its common stock on The NASDAQ Global Market had closed below the minimum \$1.00 per share required for continued inclusion under NASDAQ Marketplace Rule 4450(a)(5).

On May 16, 2008, Critical Therapeutics received notification that its stockholders' equity of \$7,126,000, as reported in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 that it filed with the SEC, does not comply with the minimum stockholders' equity requirement of \$10,000,000 for continued listing on The NASDAQ Global Market pursuant to NASDAQ Marketplace Rule 4450(a)(3).

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

### **Financial Operations Overview**

On March 13, 2007, Critical Therapeutics entered into an agreement with DEY under which Critical Therapeutics and DEY agreed to jointly promote ZYFLO and ZYFLO CR. Under the co-promotion agreement, DEY paid Critical Therapeutics a non-refundable upfront payment of \$3.0 million upon signing the co-promotion agreement, a milestone payment of \$4.0 million following approval by the FDA of the NDA for ZYFLO CR and a milestone payment of \$5.0 million following Critical Therapeutics' commercial launch of ZYFLO CR. Under the co-promotion agreement, Critical Therapeutics records all quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, up to \$1.95 million and pays DEY a commission on quarterly net sales of ZYFLO CR and ZYFLO, after third-party royalties, in excess of \$1.95 million.

In the quarters ended December 31, 2007 and March 31, 2008, Critical Therapeutics recorded an inventory reserve with respect to an aggregate of eight batches of ZYFLO CR that cannot be released into Critical Therapeutics

commercial supply chain because they did not meet Critical Therapeutics product release specifications. In conjunction with its 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 this investigation. To date, the investigation has not identified a

clear source of the issue. As of June 30, 2008, Critical Therapeutics recorded an inventory reserve with respect to seven additional batches of the tablet cores of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines. 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. As of July 18, 2008, Critical Therapeutics does not have available any additional supplies of finished ZYFLO CR tablets to ship to its wholesale distributors though eight additional batches are currently in process and may be releasable once release specification testing is completed. 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, Critical Therapeutics estimates that wholesale distributors and retail pharmacies have a sufficient inventory of ZYFLO CR to continue to provide product to patients through the end of August 2008. In April 2008, Critical Therapeutics began to reinitiate manufacture of ZYFLO, and expects to resume supply of ZYFLO in August 2008.

Critical Therapeutics established reserves of approximately \$571,000 in the fourth quarter of 2007 and \$622,000 in the first quarter of 2008 for batches that did not meet its product release specifications. If Critical Therapeutics is not able to manufacture ZYFLO CR at a commercially acceptable cost and level of supply, it 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 its product release specifications. Under Critical Therapeutics' merger agreement with Cornerstone, 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.

As it moves forward with its proposed merger with Cornerstone, Critical Therapeutics is continuing to focus on conserving cash resources and has begun to take steps to reduce spending on development programs and personnel. On May 8, 2008, as part of this effort, Critical Therapeutics announced that it had eliminated six positions, or approximately 8% of its workforce. The headcount reductions primarily affect Critical Therapeutics' research and development group. In addition, on June 12, 2008, Critical Therapeutics announced that it eliminated an additional 15 positions, or approximately 23% of its remaining workforce during the month of June. The June 2008 headcount reductions primarily affect employees performing sales and development functions. Critical Therapeutics expects to consider further reductions in headcount in additional areas of its business in the future in order to conserve cash and reduce expenses. The nature, extent and timing of future reductions will be made based on Critical Therapeutics' business needs and financial resources.

In connection with the implementation of the May 8, 2008 and June 12, 2008 reductions in its workforce, Critical Therapeutics expects to record a charge of approximately \$1.2 million of severance benefits in the second quarter of 2008. Critical Therapeutics will record the restructuring charges in accordance with Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, or SFAS 146.

On June 25, 2007, Critical Therapeutics entered into a definitive agreement with DEY to jointly promote PERFOROMIST, DEY's product for the treatment of COPD. Under the agreement, DEY granted Critical Therapeutics a right and license or sublicense to promote and detail PERFOROMIST in the United States, together with DEY. In October 2007, after expanding Critical Therapeutics' sales force to over 40 representatives, Critical Therapeutics announced that it had commercially launched PERFOROMIST with DEY. Under the agreement, DEY pays Critical Therapeutics a commission on retail sales of PERFOROMIST above a specified baseline. On July 2, 2008, Critical Therapeutics provided notice to DEY that Critical Therapeutics had exercised its contractual right to terminate the co-promotion agreement for PERFOROMIST. The termination is effective September 30, 2008.

In 2003, Critical Therapeutics entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1. Under this collaboration, MedImmune paid Critical Therapeutics initial fees of \$10.0 million in late 2003 and \$2.5 million in early 2004. In addition, MedImmune agreed to pay Critical

Therapeutics \$125,000 in 2007, \$1.0 million in 2006, \$2.75 million in 2005 and \$1.5 million in 2004 for milestone payments and to fund certain research expenses incurred by Critical Therapeutics for the HMGB1 program.

In January 2007, Critical Therapeutics entered into an exclusive license agreement with IMI under which Critical Therapeutics licensed to IMI patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. In May 2007, under the agreement with IMI, Critical Therapeutics received an initial license fee of \$500,000 in cash and IMI junior preferred stock valued at \$500,000 in connection with IMI's first financing. However, under Critical Therapeutics' license agreement with The Feinstein Institute, Critical Therapeutics was obligated to pay The Feinstein Institute \$100,000 of this cash payment and IMI junior preferred stock valued at \$100,000. Critical Therapeutics included in revenue under collaboration and license agreements in 2007 the \$1.0 million total license fee that it received from IMI and included in research and development expenses the payments of \$100,000 in cash and IMI junior preferred stock valued at \$100,000 that it made to The Feinstein Institute. These amounts were recorded in the second quarter of 2007. Under the license agreement, IMI also has agreed to pay Critical Therapeutics \$1.0 million, excluding a \$200,000 payment that Critical Therapeutics would be obligated to pay The Feinstein Institute, upon full regulatory approval of a licensed product by the FDA or a foreign counterpart agency and royalties based on a net sales of licensed products and methods by IMI and its affiliates. In March 2008, Critical Therapeutics sold the remaining 400,000 shares of junior preferred stock to two investors, which had participated in IMI's first financing, for an aggregate purchase price of \$400,000. The purchase price is subject to adjustment if these investors sell or receive consideration for these shares of junior preferred stock pursuant to an acquisition of IMI prior to February 1, 2009 at a price per share greater than they paid Critical Therapeutics.

Since its inception, Critical Therapeutics has incurred significant losses each year. Critical Therapeutics had net losses of \$37.0 million in the year ended December 31, 2007 and \$48.8 million in the year ended December 31, 2006. Critical Therapeutics had net losses of \$10.8 million in the three months ended March 31, 2008 and \$4.7 million in the three months ended March 31, 2007. As of March 31, 2008, Critical Therapeutics had an accumulated deficit of approximately \$202 million. Critical Therapeutics expects to incur significant losses for the foreseeable future and may never achieve profitability. Although the size and timing of its future operating losses are subject to significant uncertainty, Critical Therapeutics expects its operating losses to continue over the next several years as it funds its development programs, market and sell ZYFLO CR and prepare for the potential commercial launch of its product candidates. Since its inception, Critical Therapeutics has raised proceeds to fund its operations through public offerings of common stock, private placements of equity securities, debt financings, the receipt of interest income, payments from its collaborators, MedImmune and Beckman Coulter, license fees from IMI, payments from DEY under its zileuton co-promotion agreement and revenues from sales of ZYFLO and ZYFLO CR.

### ***Revenues***

From its inception on July 14, 2000 through the third quarter of 2005, Critical Therapeutics derived all of its revenues from license fees, research and development payments and milestone payments that it has received from its collaboration and license agreements with MedImmune and Beckman Coulter. In the fourth quarter of 2005, Critical Therapeutics began selling, and recognizing revenue from ZYFLO. In September 2007, Critical Therapeutics began selling, and recognizing revenue from ZYFLO CR. In 2007, Critical Therapeutics also recorded license revenue from its license agreement with IMI. In February 2008, Critical Therapeutics stopped the manufacture and supply of ZYFLO to the market. Critical Therapeutics expects to resume distribution of ZYFLO in July 2008.

### ***Cost of Products Sold***

Cost of products sold consists of manufacturing, distribution and other costs related to Critical Therapeutics commercial products, ZYFLO and ZYFLO CR. In addition, it includes royalties to third parties related to ZYFLO and ZYFLO CR and any reserves established for excess or obsolete inventory. Most of Critical Therapeutics

manufacturing and distribution costs are paid to third-party manufacturers. However, there are



some internal costs included in cost of products sold, including salaries and expenses related to managing Critical Therapeutics supply chain and for certain quality assurance and release testing costs.

### ***Research and Development Expenses***

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for monitoring and analyzing clinical trials, regulatory costs, including user fees paid to the FDA, milestone payments to third parties, costs related to the development of Critical Therapeutics approved NDA for ZYFLO CR, costs of contract research and manufacturing and the cost of facilities. In addition, research and development expenses include the cost of Critical Therapeutics medical affairs and medical information functions, which educate physicians on the scientific aspects of Critical Therapeutics commercial products and the approved indications, labeling and the costs of monitoring adverse events. After FDA approval of a product candidate, Critical Therapeutics records manufacturing expenses associated with a product as cost of products sold rather than as research and development expenses. Critical Therapeutics expenses research and development costs and patent related costs as they are incurred. Because of Critical Therapeutics ability to utilize resources across several projects, many of its research and development costs are not tied to any particular project and are allocated among multiple projects. Critical Therapeutics records direct costs on a project-by-project basis. Critical Therapeutics records indirect costs in the aggregate in support of all research and development. Development costs for clinical stage programs such as zileuton injection tend to be higher than earlier stage programs such as Critical Therapeutics HMGB1 and alpha-7 programs due to the costs associated with conducting late stage clinical trials and large-scale manufacturing.

Critical Therapeutics expects that research and development expenses relating to its portfolio will fluctuate depending primarily on the timing and outcomes of clinical trials, related manufacturing initiatives and milestone payments to third parties and the results of its decisions based on these outcomes. Critical Therapeutics expects to incur additional expenses over the next several years for clinical trials related to its product development candidates, including zileuton injection and alpha-7. Critical Therapeutics also expects manufacturing expenses for some programs included in research and development expenses to increase as it scales up production of zileuton injection for later stages of clinical development. Critical Therapeutics initiated a Phase IV clinical trial in July 2007 related to ZYFLO CR to examine its potential clinical benefits in the current patient treatment setting. In March 2008, Critical Therapeutics discontinued the trial because of patient enrollment that was significantly slower than it had anticipated. At March 31, 2008, Critical Therapeutics accrued \$1.1 million related to costs to terminate the clinical trial. These costs are included in research and development expenses for the three months ended March 31, 2008. As a result of the FDA's approval of the NDA for ZYFLO CR in May 2007, Critical Therapeutics made milestone payments totaling \$3.1 million and accrued at present value an additional \$3.5 million related to milestone obligations due on the first and second anniversary of the FDA's approval. Critical Therapeutics included these milestone payments and accruals in research and development expenses in its results for the second quarter of 2007 and included the accretion of the discount related to the present value of the milestone obligations in interest expense.

### ***Sales and Marketing Expenses***

Sales and marketing expenses consist primarily of salaries and other related costs for personnel in sales, marketing, managed care and Critical Therapeutics sales operations functions, as well as other costs related to ZYFLO CR and ZYFLO. Critical Therapeutics also incurred marketing and other costs related to its launch of ZYFLO CR in September 2007. Other costs included in sales and marketing expenses include sales and marketing costs related to Critical Therapeutics co-promotion and marketing agreement, cost of product samples of ZYFLO CR and ZYFLO, promotional materials, market research and sales meetings. Critical Therapeutics expects to continue to incur sales and marketing costs associated with enhancing Critical Therapeutics sales and marketing functions and maintaining Critical Therapeutics increased sales force to support ZYFLO CR. In addition, under its co-promotion agreement with

DEY, Critical Therapeutics has

207

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deferred the \$12.0 million in aggregate upfront and milestone payments that it received in 2007. Critical Therapeutics is amortizing these payments over the term of the agreement. The amortization of the upfront and milestone payments will offset some or all of the co-promotion fees paid to DEY for promoting ZYFLO CR and ZYFLO in future periods under the agreement. Critical Therapeutics expects to record all ZYFLO CR and ZYFLO sales generated by the combined sales force and record any co-promotion fees paid to DEY and the amortization of the upfront and milestone payments in sales and marketing.

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, accounting, legal, business development, information technology and human resource functions. Other costs included in general and administrative expenses include certain facility and insurance costs, including director and officer liability insurance, as well as professional fees for legal, consulting and accounting services.

### **Critical Accounting Policies**

The discussion and analysis of Critical Therapeutics' financial condition and results of operations are based on Critical Therapeutics' consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires Critical Therapeutics to make estimates and judgments that affect its reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, Critical Therapeutics' reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

Critical Therapeutics regards an accounting estimate or assumption underlying Critical Therapeutics' financial statements as a critical accounting estimate where:

the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

the impact of the estimates and assumptions on financial condition or operating performance is material.

Critical Therapeutics' significant accounting policies are more fully described in the notes to its consolidated financial statements included in this proxy statement/prospectus. Not all of these significant accounting policies, however, fit the definition of critical accounting estimates. Critical Therapeutics has discussed its accounting policies with the audit committee of its board of directors, and believes that its estimates relating to revenue recognition, product returns, inventory, accrued expenses, short-term investments, stock-based compensation and income taxes described below fit the definition of critical accounting estimates.

### ***Revenue Recognition***

Critical Therapeutics sells ZYFLO CR and ZYFLO primarily to pharmaceutical wholesalers, distributors and pharmacies, which have the right to return purchased product. Critical Therapeutics commercially launched ZYFLO in October 2005 and ZYFLO CR in September 2007. Critical Therapeutics recognizes revenue from product sales in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, or SFAS No. 48, which requires the amount of future returns to be reasonably estimated. Critical Therapeutics recognizes product sales net of estimated allowances for product returns, estimated rebates in connection with contracts relating to managed care, Medicaid, Medicare, and estimated chargebacks from distributors and prompt payment and other discounts.

Prior to the first quarter of 2007, Critical Therapeutics deferred the recognition of revenue on ZYFLO product shipments to wholesale distributors until units were dispensed through patient prescriptions as it was unable to reasonably estimate the amount of future product returns. Units dispensed are not generally subject to return. In the first quarter of 2007, based on its product return experience since it launched ZYFLO in October 2005,

Critical Therapeutics began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties, as sufficient history existed to make such estimates. In connection with this change in estimate, Critical Therapeutics recorded an increase in net product sales in 2007 related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. This change in estimate totaled approximately \$953,000 and was reported in Critical Therapeutics' results for the first quarter of 2007. Critical Therapeutics anticipates that the rate of return for ZYFLO CR will be comparable to the historical rate of return for ZYFLO. As a result, Critical Therapeutics recognizes revenue for sales of ZYFLO CR upon shipment to third parties and records a reserve for potential returns from these third parties based on its product returns experience with ZYFLO and other factors.

Under its collaboration agreements with MedImmune and Beckman Coulter, Critical Therapeutics is entitled to receive non-refundable license fees, milestone payments and other research and development payments. Payments received are initially deferred from revenue and subsequently recognized in Critical Therapeutics' statements of operations when earned. Critical Therapeutics must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by its collaborators. Critical Therapeutics recognizes these revenues over the estimated performance period as set forth in the contracts based on proportional performance adjusted from time to time for any delays or acceleration in the development of the product. Because MedImmune and Beckman Coulter can each cancel its agreement with it, Critical Therapeutics does not recognize revenues in excess of cumulative cash collections. It is difficult to estimate the impact of the adjustments on the results of Critical Therapeutics' operations because, in each case, the adjustment is limited to the cash received.

Under its license agreement with IMI, Critical Therapeutics included in revenue from collaboration and license agreements in the second quarter of 2007 a \$1.0 million initial license fee that it received from IMI and included in research and development expenses a related \$100,000 cash payment and IMI preferred stock payment valued at \$100,000 that it made to The Feinstein Institute.

### ***Product Returns***

Consistent with industry practice, Critical Therapeutics offers customers the ability to return products during the six months prior to, and the 12 months after, the product expires. At the time of its commercial launch in October 2005, Critical Therapeutics began shipping ZYFLO with an expiration date of 12 months. Since its launch of ZYFLO, Critical Therapeutics has extended ZYFLO's expiration date from 12 months to 24 months as of March 31, 2008. In September 2007, Critical Therapeutics launched ZYFLO CR, which currently has an expiration date of 18 months. Critical Therapeutics anticipates that the rate of return for ZYFLO CR will be comparable to the historical rate of return for ZYFLO. Critical Therapeutics may adjust its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include Critical Therapeutics' estimate of inventory levels of its products in the distribution channel, the shelf-life of the product shipped, competitive issues such as new product entrants and other known changes in sales trends. Critical Therapeutics evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve accordingly. As a result of this ongoing evaluation, Critical Therapeutics' product return reserve was \$286,000 as of March 31, 2008, which was comprised of a product return reserve of approximately \$177,000 for ZYFLO and \$109,000 for ZYFLO CR. Critical Therapeutics' allowance for ZYFLO product returns includes \$165,000 of product in its distribution channel that it does not expect to be dispensed through prescriptions in the second quarter of 2008 as a result of its decision to cease promotion of ZYFLO in February 2008. In the first quarter of 2008, as a result of stronger than expected ZYFLO prescriptions, Critical Therapeutics reduced its product return reserve for ZYFLO by \$440,000. Critical Therapeutics expects to resume supply of ZYFLO in July 2008. As a result, Critical Therapeutics will need to evaluate its estimate of product returns for the reintroduction of ZYFLO to the market.



### ***Inventory***

Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out, or FIFO, method. Critical Therapeutics' estimate of the net realizable value of its inventories is subject to judgment and estimation. The actual net realizable value of Critical Therapeutics' inventories could vary significantly from its estimates and could have a material effect on Critical Therapeutics' financial condition and results of operations in any reporting period. Critical Therapeutics determines the estimated useful life of its inventory based upon stability data of the underlying product stored at different temperatures or in different environments. As of March 31, 2008, inventory consists of API, which is raw material in powder form, work-in-process and finished tablets to be used for commercial sale. On a quarterly basis, Critical Therapeutics analyzes its inventory levels and writes down inventory that has become obsolete, inventory that has a cost basis in excess of Critical Therapeutics' expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. At March 31, 2008, Critical Therapeutics had an inventory reserve of \$1.2 million. The inventory reserve includes \$571,000 recorded in the fourth quarter of 2007 and \$622,000 recorded in the first quarter of 2008 relating to batches that did not meet Critical Therapeutics' product release specifications for ZYFLO CR. In addition, Critical Therapeutics anticipates that, as a result of the timing of its ongoing investigation, it will need to reserve for additional inventory that is unlikely to be sold. As of March 31, 2008, Critical Therapeutics had \$9.7 million in inventory net of the inventory reserve. Critical Therapeutics expects its inventory levels to decrease in the second and third quarters of 2008.

### ***Accrued Expenses***

As part of the process of preparing Critical Therapeutics' consolidated financial statements, Critical Therapeutics is required to estimate certain expenses. This process involves identifying services that have been performed on Critical Therapeutics' behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in Critical Therapeutics' consolidated financial statements. Examples of estimated expenses for which Critical Therapeutics accrues include professional service fees, such as fees paid to lawyers and accountants, rebates to third parties, including government programs such as Medicaid or private insurers, contract service fees, such as amounts paid to clinical monitors, data management organizations and investigators in connection with clinical trials, fees paid to contract manufacturers in connection with the production of clinical materials, license fees in connection with the achievement of milestones and restructuring charges.

In connection with rebates, Critical Therapeutics' estimates are based on its estimated mix of sales to various third-party payors, which are either contractually or statutorily entitled to certain discounts off Critical Therapeutics' listed price of ZYFLO and ZYFLO CR. In the event that Critical Therapeutics' sales mix to certain third-party payors is different from its estimates, Critical Therapeutics may be required to pay higher or lower total rebates than it has estimated. In connection with service fees, Critical Therapeutics' estimates are most affected by its understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of Critical Therapeutics' service providers invoice it monthly in arrears for services performed; however, certain service providers invoice it based upon milestones in its agreements with them. In the event that it does not identify certain costs that it has begun to incur, or, under or over-estimates the level of services performed or the costs of such services, Critical Therapeutics' reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often subject to judgment. Critical Therapeutics makes these judgments based upon the facts and circumstances known to it in accordance with generally accepted accounting principles.

### ***Investments***

Investments consist primarily of U.S. government treasury and agency notes, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, each of investment-grade quality, which have an

original maturity date greater than 90 days. These investments are recorded at fair value and accounted for as available-for-sale securities. Critical Therapeutics records any unrealized gain (loss) during



the year as an adjustment to stockholders' equity unless it determines that the unrealized gain (loss) is not temporary. Critical Therapeutics adjusts the original cost of debt securities for amortization of premiums and accretion of discounts to maturity. Because Critical Therapeutics has determined that the unrealized gain (loss) on its investments has been temporary, it has not recorded any impairment losses since inception.

It is Critical Therapeutics' intent to hold its investments until such time as it intends to use them to meet the ongoing liquidity needs of its operations. However, if the circumstances regarding an investment, such as a change in an investment's external credit rating, or its liquidity needs were to change, Critical Therapeutics would consider a sale of the related security prior to the maturity of the underlying investment to minimize any losses. At March 31, 2008, Critical Therapeutics held \$287,000 in auction rate securities. In February 2008, Critical Therapeutics was informed that there was insufficient demand at auction for these securities. As a result, this amount is currently not liquid and may not become liquid unless the issuer is able to refinance it. Critical Therapeutics has classified its investment in auction rate securities as a long-term investment and has included the amount in other assets on its balance sheet.

### ***Stock-Based Compensation***

Critical Therapeutics applies the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123(R), using the modified prospective application method, which requires it to recognize compensation cost for granted, but unvested awards (upon adoption), new awards and awards modified, repurchased, or cancelled after adoption under the fair value method.

Critical Therapeutics accounts for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS 123(R). Critical Therapeutics uses the Black-Scholes option-pricing model to calculate the fair value of stock-based compensation under SFAS 123(R). There are a number of assumptions used to calculate the fair value of stock options or restricted stock issued to employees under this pricing model.

The two factors that most affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded and the volatility of such fair value. Accounting for equity instruments granted by Critical Therapeutics under SFAS 123(R) and the Emerging Issues Task Force-Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or EITF 96-18, requires fair value estimates of the equity instrument granted. If Critical Therapeutics' estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services can be readily estimated, Critical Therapeutics uses the value of such goods or services to determine the fair value of the equity instruments. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services cannot be readily estimated, as is true in connection with most stock options and warrants granted to employees or non-employees, Critical Therapeutics estimates the fair value of the equity instruments based upon the consideration of factors that it deems to be relevant at the time using cost, market or income approaches to such valuations.

### ***Income Taxes***

As part of the process of preparing its consolidated financial statements, Critical Therapeutics is required to estimate its income taxes in each of the jurisdictions in which it operates. This process involves estimating Critical Therapeutics' actual current tax exposure together with assessing temporary differences resulting from differing treatments of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. In

addition, as of March 31, 2008, Critical Therapeutics had federal and state tax net operating loss carryforwards of approximately \$172 million, which expire beginning in 2021 and 2008, respectively. Critical Therapeutics also has research and experimentation credit carryforwards of approximately \$1.9 million as of March 31, 2008, which expire beginning in 2021. Critical Therapeutics has recorded a full valuation

allowance as an offset against these otherwise recognizable net deferred tax assets due to the uncertainty surrounding the timing of the realization of the tax benefit. In the event that Critical Therapeutics determines in the future that it will be able to realize all or a portion of a net deferred tax benefit, an adjustment to deferred tax valuation allowance would increase net income or additional paid in capital for deferred tax assets related to stock compensation deductions in the period in which such a determination is made. The Tax Reform Act of 1986 contains provisions that may limit the utilization of net operating loss carryforwards and credits available to be used in any given year in the event of significant changes in ownership interest, as defined.

Critical Therapeutics did not recognize any accrued interest and penalties related to unrecognized tax benefits, as no amounts would be due as a result of its net tax loss carryforward. Critical Therapeutics' policy is to record interest and penalties related to unrecognized tax benefits in income tax expense. Tax years for 2000 to 2007 remain subject to examination for federal and numerous state jurisdictions. The primary state tax jurisdiction to which Critical Therapeutics is subject is the Commonwealth of Massachusetts.

## **Results of Operations**

### ***Three Months Ended March 31, 2008 and 2007***

#### *Revenues*

*Revenue from Product Sales.* Critical Therapeutics recognized revenue from product sales of ZYFLO CR and ZYFLO of \$3.3 million in the three months ended March 31, 2008, compared to \$2.9 million from product sales of ZYFLO in the three months ended March 31, 2007. The increase in product revenue was primarily attributable to a 49% increase in prescription volume, a 11.3% price increase in ZYFLO's and ZYFLO CR's wholesale acquisition price over the corresponding period in 2007 and a \$440,000 reduction in Critical Therapeutics' product return reserve for ZYFLO as a result of stronger than expected ZYFLO prescriptions. In addition, in the three months ended March 31, 2007, Critical Therapeutics recorded a \$953,000 increase in product sales related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. On January 1, 2007, based on its product return experience since its launch of ZYFLO in October 2005, Critical Therapeutics began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties, as it is now able to estimate product returns.

*Revenue under Collaboration Agreements.* Critical Therapeutics did not recognize any collaboration revenue in the three months ended March 31, 2008. Critical Therapeutics recognized \$601,000 in collaboration revenue in the three months ended March 31, 2007. Collaboration revenue for the three months ended March 31, 2007 was primarily due to the recognition of \$400,000 of deferred revenue recognized under its collaboration agreement with Beckman Coulter for a license fee paid to advance into formal product development a diagnostic assay in connection with its HMGB1 program. Collaboration revenue also included approximately \$201,000 related to a portion of the \$12.5 million of initial fees MedImmune paid to Critical Therapeutics that Critical Therapeutics recognized over the duration of the contract and the \$5.3 million cumulatively billed to MedImmune for milestone payments and development support from the inception of the agreement through March 31, 2007. At March 31, 2008, Critical Therapeutics had no deferred collaboration revenue and had completed the research term of its agreement with MedImmune. Critical Therapeutics' revenue recognized from existing collaborations for the remainder of 2008 is likely to decline substantially compared to corresponding periods in 2007 because it has now recognized all of the revenue that it had previously deferred. Going forward, Critical Therapeutics' revenue from collaboration agreements will fluctuate each quarter and will be highly dependent upon the achievement of milestones under its existing agreements, or will be dependent upon its entering into new collaboration agreements.

#### *Costs and Expenses*

*Cost of Products Sold.* Cost of products sold in the three months ended March 31, 2008 was \$1.8 million, compared to \$741,000 in the three months ended March 31, 2007. Gross margin was 45% for the three months ended March 31, 2008 and 74% for the three months ended March 31, 2007. Cost of products sold in

the three months ended March 31, 2008 consisted of the expenses associated with manufacturing ZYFLO CR and distributing ZYFLO and ZYFLO CR, royalties to Abbott and Jagotec related to ZYFLO and ZYFLO CR and reserves established for excess or obsolete inventory. Cost of products sold in the three months ended March 31, 2007 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO. As a result of Critical Therapeutics' change in estimates relating to recognition of ZYFLO sales, Critical Therapeutics recorded an additional \$166,000 in cost of products sold in the three months ended March 31, 2007. Critical Therapeutics recorded inventory reserves of \$609,000 for the three months ended March 31, 2008. The write-offs in 2008 resulted from certain batches of ZYFLO CR that did not meet Critical Therapeutics' product release specifications. Critical Therapeutics did not record any inventory reserves during the three months ended March 31, 2007. As a result of its commercial launch of ZYFLO CR in September 2007, Critical Therapeutics' gross margins, excluding write-offs, will likely decrease as a result of an increase in cost of products sold related to ZYFLO CR due to the more complex manufacturing process and supply chain for ZYFLO CR and additional royalty obligations to Abbott and to Jagotec for utilization of its controlled-release technology. In the near term, this decrease in gross margin will be offset, in part, by the reinitiation of ZYFLO to the market. This likely decrease could be offset, in part, by an increase in Critical Therapeutics' wholesale acquisition price of ZYFLO CR and its ability to spread some of its fixed costs associated with managing its supply chain over a larger revenue base in 2008.

*Research and Development Expenses.* Research and development expenses in the three months ended March 31, 2008 were \$5.4 million, compared to \$2.9 million in the three months ended March 31, 2007, an increase of approximately \$2.5 million, or 84%. This increase was primarily due to higher expenses associated with Critical Therapeutics' ZYFLO CR Phase IV and zileuton injection clinical trials, offset, in part, by lower expenses associated with Critical Therapeutics' alpha-7 and HMGB1 preclinical programs.

The following table summarizes the primary components of Critical Therapeutics' research and development expenses for the three months ended March 31, 2008 and 2007:

	<b>Three Months Ended March 31, 2008      2007 (In thousands)</b>	
Zileuton (ZYFLO and ZYFLO CR)	\$ 3,254	\$ 1,335
Zileuton injection	1,046	156
Alpha-7	593	833
HMGB1		119
General research and development expenses	233	235
Stock-based compensation expense	238	240
Total research and development expenses	\$ 5,364	\$ 2,918

The following summarizes the expenses associated with Critical Therapeutics' primary research and development programs:

*Zileuton (ZYFLO and ZYFLO CR).* During the three months ended March 31, 2008, Critical Therapeutics incurred \$3.3 million in expenses related to its orally-dosed zileuton programs, including ZYFLO and ZYFLO CR, compared to \$1.3 million during the three months ended March 31, 2007, a 144% increase. This

increase was primarily due to a \$2.2 million increase in clinical, manufacturing and consulting costs related to Critical Therapeutics Phase IV clinical trial for ZYFLO CR. This increase was partially offset by a \$267,000 reduction in salaries and other personnel related costs as a result of Critical Therapeutics December 2006 restructuring and a reduction in associated facilities and overhead costs.

Critical Therapeutics anticipates that its research and development expenses related to its ZYFLO CR program for 2008 will consist primarily of costs related to its Phase IV clinical trial for ZYFLO CR, which it discontinued in March 2008. In addition, Critical Therapeutics expects to continue to incur

certain research and development expenses to maintain and operate its medical information and pharmacovigilance functions in support of ZYFLO CR.

*Zileuton Injection.* During the three months ended March 31, 2008, Critical Therapeutics incurred \$1.0 million in expenses related to its zileuton injection program, compared to \$156,000 during the three months ended March 31, 2007, a 571% increase. This increase was primarily due to costs related to Critical Therapeutics Phase II clinical trial for zileuton injection, which began in October 2007. Critical Therapeutics expects to incur additional costs associated with the development of zileuton injection during the second quarter of 2008 as it completes the analysis of the data and prepares to report the results of its Phase II clinical trial. Critical Therapeutics currently expects to seek a collaborator for its zileuton injection program to develop and commercialize a possible product candidate.

*Alpha-7.* During the three months ended March 31, 2008, Critical Therapeutics incurred \$593,000 in expenses related to its alpha-7 program, compared to \$833,000 during the three months ended March 31, 2007, a 29% decrease. This decrease was primarily due to a reduction in the number of employees working on the program and a reduction in associated facilities and overhead costs. Critical Therapeutics anticipates that the research and development expenses for its alpha-7 program will not grow substantially in the remainder of 2008, as it expects increased costs related to preclinical studies conducted by third parties to advance its lead molecule to be offset by the reduced number of employees working on this program. Critical Therapeutics anticipates that significant additional expenditures will be required to advance any product candidate through preclinical and clinical development. Critical Therapeutics currently expects to seek a collaborator for its alpha-7 program to develop and commercialize possible product candidates prior to human clinical trials. However, because this project is at a very early stage, the actual costs and timing of research, preclinical development, clinical trials and associated activities are highly uncertain, subject to risk, and will change depending upon the product candidate it chooses to develop, the clinical indications developed, the development strategy adopted, and the terms of a collaboration, if it is able to enter into one. As a result, Critical Therapeutics is unable to estimate the costs or the timing of advancing a small molecule from its alpha-7 program through clinical development.

*HMGB1.* During the three months ended March 31, 2008, Critical Therapeutics did not incur any expenses related to its HMGB1 program, compared to \$119,000 in expenses during the three months ended March 31, 2007. Critical Therapeutics has not conducted, and currently does not anticipate conducting, significant research and development activities relating to HMGB1 in 2008. In addition, a larger portion of the expenses in Critical Therapeutics HMGB1 program will be assumed by MedImmune as the program advances into later stages of preclinical development. Because the HMGB1 program is still in preclinical development, the actual costs and timing of preclinical development, clinical trials and associated activities are highly uncertain, subject to risk and will change depending upon the clinical indications developed and the development strategy adopted. A significant amount of these clinical trial costs will be incurred by MedImmune. The expenses for HMGB1 are reflected in the accompanying statements of operations as part of research and development expenses, while any funding received from MedImmune and Beckman Coulter to support Critical Therapeutics research efforts is included in revenue under collaboration agreements.

General research and development expenses, which are not allocated to any specific program, remained consistent in the three months ended March 31, 2008 as compared to the three months ended March 31, 2007. Critical Therapeutics general research and development expenses, which are incurred in support of all of its research and development programs, are not easily allocable to any individual program, and therefore, have been included in general research and development expenses. In addition, Critical Therapeutics stock-based compensation expense remained consistent in the three months ended March 31, 2008, compared to the three months ended March 31, 2007.

*Sales and Marketing.* Sales and marketing expenses for the three months ended March 31, 2008 were \$3.9 million, compared to \$2.0 million for the three months ended March 31, 2007. The \$1.9 million increase was primarily attributable to a \$765,000 increase in salary and other employee related costs of employees



performing sales and marketing functions, an increase of approximately \$1.4 million related to promotional materials, advertising and other costs associated with ZYFLO CR that Critical Therapeutics incurred to support its co-promotion agreement with DEY and an increase of approximately \$200,000 in co-promotion fees paid to DEY in accordance its co-promotion agreement. These increases were partially offset by a decrease of \$534,000 related to amortization of Critical Therapeutics' deferred sales and marketing expense. The number of employees performing sales and marketing functions increased to 49 employees at March 31, 2008 from 26 employees at March 31, 2007. Critical Therapeutics expects that its sales and marketing costs will decrease during the remainder of 2008 as it focuses on conserving cash resources.

*General and Administrative Expenses.* General and administrative expenses for the three months ended March 31, 2008 were \$3.2 million, compared to \$3.1 million for the three months ended March 31, 2007. The increase was primarily due to an increase of \$324,000 in legal fees primarily related to Critical Therapeutics' review of strategic alternatives and an increase of \$208,000 related to the additional bonus paid in February 2008 in accordance with its agreement with its former President and Chief Executive Officer. These increases were offset, in part, by a decrease of \$232,000 in advisory fees paid in connection with the signing of Critical Therapeutics' agreement with DEY in the first quarter of 2007 and a decrease of \$190,000 in stock-based compensation. The number of employees performing general and administrative functions was 13 employees at March 31, 2008 and 14 employees at March 31, 2007. Critical Therapeutics expects that its general and administrative expenses will increase during the remainder of 2008 compared to corresponding periods in 2007 as it incurs professional fees relating to its proposed merger with Cornerstone.

*Other Income.* Interest income for the three months ended March 31, 2008 was \$218,000, compared to \$590,000 for the three months ended March 31, 2007. The decrease was primarily attributable to lower average cash and investment balances and lower interest rates. Interest expense amounted to \$49,000 for the three months ended March 31, 2008 and \$39,000 for the three months ended March 31, 2007. Interest expense primarily relates to the accretion of the discount on Critical Therapeutics' accrued first and second anniversary milestone payments owed to Abbott and Jagotec as a result of the FDA approval of the NDA for ZYFLO CR and borrowings under Critical Therapeutics' loan with Silicon Valley Bank for capital expenditures.

### ***Years Ended December 31, 2007 and 2006***

#### *Revenues*

*Revenue from Product Sales.* Critical Therapeutics recognized revenue from net product sales related to sales of ZYFLO and ZYFLO CR of \$11.0 million in 2007 compared to \$6.6 million in 2006, an increase of 66%. The increase in product revenue is primarily attributable to an 11% increase in ZYFLO prescription volume, an 11% increase in ZYFLO's wholesale acquisition price and \$2.3 million in net product sales of ZYFLO CR after its launch in September 2007. In addition, in the first quarter of 2007 Critical Therapeutics recorded a \$953,000 increase in product sales related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns.

*Revenue under Collaboration and License Agreements.* Critical Therapeutics recognized collaboration and license revenues of \$1.9 million in 2007 compared to \$6.4 million in 2006, a decrease of approximately \$4.6 million, or 71%. This decrease was primarily due to a \$5.6 million decrease in collaboration revenue from Critical Therapeutics' collaborations with MedImmune and Beckman Coulter, offset by \$1.0 million in license revenue related to its agreement with IMI. Critical Therapeutics did not recognize any license revenue from IMI in the year ended December 31, 2006. For 2007, Critical Therapeutics recognized collaboration revenue of \$800,000. Critical Therapeutics' 2007 collaboration revenue also included:

\$400,000 of previously deferred revenue recognized under its collaboration agreement with Beckman Coulter for a license fee paid to advance into formal product development a diagnostic assay in connection with Critical Therapeutics HMGB1 program;

approximately \$400,000 related to a portion of the \$12.5 million of initial fees MedImmune paid to Critical Therapeutics that it recognized over the duration of the agreement with MedImmune; and

the \$5.4 million cumulatively billed to MedImmune for milestone payments and development support from the inception of the agreement with MedImmune through December 31, 2007.

Collaboration revenue for the year ended December 31, 2006 was primarily comprised of the portion of the initial fees MedImmune paid to Critical Therapeutics that it recognized in each period, and the portion of milestone payments and development support billed to MedImmune.

Since it entered into the agreement with MedImmune in 2003, Critical Therapeutics has billed a total of \$17.9 million to MedImmune, consisting of the \$12.5 million initial payment, a \$1.3 million milestone payment and \$4.1 million of development support. As of December 31, 2007, Critical Therapeutics has recognized this entire amount as collaboration revenue. At December 31, 2007, Critical Therapeutics had no deferred collaboration revenue and had completed the research term of Critical Therapeutics' agreement with MedImmune. Critical Therapeutics' revenue recognized from existing collaborations in 2008 may decline substantially because it has now recognized all of the revenue that it had previously deferred. Going forward, Critical Therapeutics' revenue from collaboration agreements will fluctuate each quarter and will be highly dependent upon the achievement of milestones under its existing agreements, or will be dependent upon its entering into new collaboration agreements.

#### *Costs and Expenses*

*Cost of Products Sold.* Cost of products sold in 2007 was \$4.2 million, compared to \$2.2 million in 2006. Gross margin was 62% for 2007 and 66% for 2006. Cost of products sold in 2007 consisted of the expenses associated with manufacturing and distributing ZYFLO and ZYFLO CR, royalties to Abbott and Jagotec related to ZYFLO and ZYFLO CR and reserves established for excess or obsolete inventory. As a result of its change in estimates relating to recognition of ZYFLO sales, Critical Therapeutics recorded an additional \$166,000 in cost of products sold for 2007. Cost of products sold in 2006 consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO. Critical Therapeutics recorded inventory write-offs of \$821,000 for 2007 and \$299,000 for 2006. The write-offs in 2007 and 2006 resulted from excess or obsolete inventory that could no longer be used for commercial sale.

*Research and Development Expenses.* Research and development expenses in 2007 were \$21.7 million compared to \$26.9 million in 2006, a decrease of approximately \$5.2 million, or 20%. This decrease was primarily due to lower expenses associated with clinical trials, as well as the reduction in the number of employees performing research and development functions following Critical Therapeutics' 2006 restructurings, offset, in part, by \$6.6 million in milestone payments paid and accrued for during 2007 as a result of the FDA's approval of the NDA for ZYFLO CR in May 2007.

The following table summarizes the primary components of Critical Therapeutics' research and development expenses for the years ended December 31, 2007 and 2006:

	<b>Year Ended December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>	
Zileuton (ZYFLO and ZYFLO CR)	\$ 14,479	\$ 11,975
Zileuton injection	1,373	2,336
CTI-01	(77)	2,960

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Alpha-7	3,239	3,903
HMGB1	343	1,829
General research and development expenses	1,275	2,600
Stock-based compensation expense	1,023	1,309
Total research and development expenses	\$ 21,655	\$ 26,912

The following summarizes the expenses associated with Critical Therapeutics' primary research and development programs:

*Zileuton (ZYFLO and ZYFLO CR).* During 2007, Critical Therapeutics incurred \$14.5 million in expenses related to its orally-dosed zileuton programs, including ZYFLO and ZYFLO CR, compared to \$12.0 million during 2006, a 21% increase. This increase was primarily due to the following:

\$3.1 million in milestone fees paid to third parties as a result of the FDA's approval of the NDA for ZYFLO CR in May 2007;

\$3.5 million in accrued milestone payments to third parties as a result of the FDA's approval of the NDA for ZYFLO CR in May 2007, which are due on the first and second year anniversary of the FDA's approval;

\$2.2 million increase in clinical and manufacturing costs related to its Phase IV clinical trial for ZYFLO CR; and

\$863,000 increase in clinical and manufacturing costs related to its R(+) isomer program for zileuton.

The increases in the costs described above were partially offset by the following:

\$2.6 million reduction in clinical and manufacturing costs for ZYFLO and Critical Therapeutics' NDA registration batches for ZYFLO CR;

\$1.9 million reduction in milestone fees paid to third parties as a result of the filing of the ZYFLO CR NDA in July 2006;

\$1.2 million reduction in operating expenses incurred by its medical affairs and medical information functions, related to its scientific support of ZYFLO, as a result of its 2006 restructurings;

\$1.2 million reduction in salaries, other personnel related costs and overhead related to its 2006 restructurings; and

\$305,000 reduction in consulting and scientific advisor fees related to the ZYFLO CR NDA registration batches.

Critical Therapeutics anticipates that its research and development expenses related to its ZYFLO CR program for 2008 will consist primarily of costs related to its Phase IV clinical trial for ZYFLO CR, which it discontinued in March 2008.

*Zileuton Injection.* During 2007, Critical Therapeutics incurred \$1.4 million in expenses related to its zileuton injection program, compared to \$2.3 million during 2006, a decrease of \$963,000, or 41%. This decrease was primarily due to a reduction in clinical trial expenses related to its Phase I/II clinical trial, which concluded in the first half of 2006, offset by costs related to the preparation and initiation of its Phase II clinical trial in October 2007.

*CTI-01.* During 2007, Critical Therapeutics received a net credit of \$77,000 related to clinical trial costs associated with its CTI-01 program, compared to expenses of \$3.0 million in 2006. The costs incurred in 2006 related primarily to the enrollment and conduct of a Phase II clinical trial of CTI-01 in patients undergoing major cardiac surgery including the use of a cardiopulmonary bypass machine. Effective February 2007,

Critical Therapeutics terminated its license agreements with the University of Pittsburgh and Xanthus Pharmaceuticals related to the development of CTI-01.

*Alpha-7.* During 2007, Critical Therapeutics incurred \$3.2 million in expenses related to its alpha-7 program, compared to \$3.9 million during 2006, a 17% decrease. This decrease was primarily due to a reduction in the number of employees working on the program following Critical Therapeutics' October 2006 restructuring.

*HMGB1.* During 2007, Critical Therapeutics incurred \$343,000 in expenses related to its HMGB1 program, compared to \$1.8 million during 2006, an 81% decrease. This decrease was primarily due to lower license fees, sponsored research and laboratory supplies for Critical Therapeutics' continued

testing under its collaboration agreement with MedImmune, as well as lower personnel costs devoted to this program.

Critical Therapeutics' general research and development expenses, which are not allocated to any specific program, were \$1.3 million in 2007 compared to \$2.6 million in 2006, a decrease of 51%. This decrease was primarily due to improved methods of allocating Critical Therapeutics' research and development overhead expenses to its various programs, including costs related to personnel, laboratory and other facility costs offset, in part, by its impairment of certain laboratory equipment as a result of its abandoning a substantial portion of its current facility. Unallocated facility related costs were \$180,000 in 2007, compared to \$635,000 in 2006. In addition, unallocated fixed asset impairment and lease abandonment charges were \$664,000 in 2007. The remaining general research and development expenses, which are incurred in support of all of Critical Therapeutics' research and development programs, are not easily allocable to any individual program, and therefore, have been included in general research and development expenses.

Stock-based compensation expense that related to research and development decreased \$286,000 from \$1.3 million in 2006 to \$1.0 million in 2007. This includes expenses under SFAS 123(R) for employee grants as well as grants made to non-employees who are primarily working on research and development activities. The adjustment to stock-based compensation expense for non-employees is calculated based on the change in fair value of Critical Therapeutics' common stock during the period. The decrease in stock-based compensation expense is related primarily to May 2006 and October 2006 reductions in Critical Therapeutics' research and development personnel.

*Sales and Marketing Expenses.* Sales and marketing expenses for 2007 were \$12.2 million, compared to \$18.3 million for 2006. The \$6.1 million, or 33%, decrease in 2007 was primarily attributable to the following:

- a decrease of approximately \$4.3 million in salary and other costs related to the May 2006 and October 2006 reductions in Critical Therapeutics' specialty sales force and sales and customer management team;

- a decrease of \$1.3 million in employee travel and other employee expenses following its personnel reductions in 2006;

- a decrease of \$903,000 in infrastructure costs to support the sales force, including leased vehicle, computer and software costs;

- a decrease of \$567,000 related to amortization of its deferred sales and marketing expense;

- a decrease of \$302,000 in severance costs and \$525,000 of lower stock-based compensation expense related to the departure of its former Senior Vice President of Sales and Marketing in 2006; and

- a decrease of \$222,000 in stock-based compensation expense primarily related to its employee reductions in 2006.

The decreases were offset, in part, by the following:

- an increase of approximately \$1.5 million related to promotional materials, advertising and other costs associated with the launch of ZYFLO CR that Critical Therapeutics incurred to support its co-promotion agreement with DEY; and

- \$680,000 in co-promotion fees paid to DEY in accordance Critical Therapeutics' co-promotion agreement.

In May and October 2006, Critical Therapeutics reduced the size of its sales and marketing efforts substantially to bring its cost structure more in-line with the expected future revenue for ZYFLO. In connection with these two restructurings, Critical Therapeutics reduced the size of its sales force promoting ZYFLO from approximately 80 sales representatives at the beginning of 2006 to 18 sales representatives at December 31, 2006. In addition, Critical Therapeutics reduced the size of the sales management team, its customer management, sales operations and marketing functions. In February 2008, Critical Therapeutics



ceased manufacturing and supplying ZYFLO. In connection with its launch of ZYFLO CR in September of 2007, Critical Therapeutics increased its sales force from 18 sales representatives at the beginning of 2007 to approximately 41 sales representatives at December 31, 2007.

*General and Administrative Expenses.* General and administrative expenses for 2007 were \$13.6 million compared to \$13.5 million for 2006. The \$116,000, or 1%, increase in 2007 was primarily attributable to the following:

an increase of \$1.2 million in advisory fees paid in connection with the upfront and milestones payments that DEY paid Critical Therapeutics in 2007;

an increase of \$529,000 in consulting and other expenses primarily related to its review of strategic alternatives;

an increase of \$503,000 in legal fees primarily related to its review of strategic alternatives;

an increase of \$417,000 related to the additional bonus accrued at December 31, 2007 in accordance with its agreement with its then-current President and Chief Executive Officer;

an increase of \$199,000 in audit and accounting related fees primarily related to its 2007 filing on Form S-3, its co-promotion agreement with DEY and its first 401(k) audit; and

an increase of \$196,000 in overhead and facility related charges as a result of its facility abandonment that are allocated to general and administrative expenses.

The increases were offset, in part, by the following:

\$670,000 of severance costs and \$1.3 million of stock-based compensation expense related to the departure of its former President and Chief Executive Officer in June 2006;

\$370,000 related to stock-based compensation as a result of its May 2006 and October 2006 restructurings; and

\$351,000 in salary and other related costs as a result of the May 2006 and October 2006 employee reductions.

*Restructuring Charges.* Restructuring charges totaled \$3.5 million in 2006 related to actions Critical Therapeutics took in May and October 2006. In May 2006, Critical Therapeutics recorded charges of \$499,000 for a restructuring of its operations that was intended to better align costs with revenue and operating expectations. In October 2006, Critical Therapeutics announced a second restructuring of its operations to focus its resources on the commercialization of ZYFLO CR and on the clinical development of zileuton injection and to significantly reduce its net cash expenditures through lower spending on its existing sales force as well as on its discovery and research programs. The restructuring charges for 2006 were comprised of the following:

severance, benefit and related payments of approximately \$2.1 million;

asset impairment charges of \$501,000 related to computer and laboratory equipment with a net realizable value below its net book value;

stock-based compensation expense of \$622,000 related to the acceleration of vesting of stock options from the departure of Critical Therapeutics former Senior Vice President of Research and Development and Chief Scientific Officer; and

approximately \$335,000 related to the termination of leases on vehicles used by its sales force and outplacement services.

The restructuring charges for 2006 do not include approximately \$972,000 of severance expenses and \$1.8 million of stock-based compensation related to the departures of Critical Therapeutics' former President and Chief Executive Officer and its former Senior Vice President of Sales and Marketing. These amounts have been included in general and administrative expenses and sales and marketing expenses, as described

previously. As of December 31, 2007, Critical Therapeutics had completed the implementation of these restructurings and paid all restructuring costs.

#### *Other*

*Other Income.* Interest income in 2007 was \$2.0 million, compared to \$2.7 million in 2006. The decrease was primarily attributable to a lower average cash and investment balance during 2007. Interest expense amounted to \$209,000 in 2007 and \$214,000 in 2006. The interest expense relates to borrowings under Critical Therapeutics' loan with Silicon Valley Bank for capital expenditures and the accretion of the discount on its accrued first and second anniversary milestone payments owed to Abbott and Jagotec as a result of the FDA approval of the NDA for ZYFLO CR.

#### ***Years Ended December 31, 2006 and 2005***

##### *Revenues*

*Revenue from Product Sales.* Critical Therapeutics recognized revenue from product sales related to sales of ZYFLO of \$6.6 million in 2006 compared to \$387,000 in 2005. Product sales in 2005 reflect the period from launch in October through the end of the year. Under SFAS No. 48, Critical Therapeutics recognizes revenue from product shipments when it has determined the right to return the product has lapsed or when it can reasonably estimate returns relating to the shipments to third parties. In accordance with SFAS No. 48, in 2005 and 2006, Critical Therapeutics deferred recognition of revenue on product shipments of ZYFLO to wholesalers, distributors and pharmacies until the product was dispensed through patient prescriptions. Shipments of ZYFLO to third parties that had not been recognized as revenue totaled \$1.2 million as of December 31, 2006 and \$1.7 million as of December 31, 2005 and were included in deferred product revenue on Critical Therapeutics' balance sheet. Critical Therapeutics deferred the cost of product shipped to third parties that had not been recognized as revenue in accordance with its revenue recognition policy until the product was dispensed through patient prescriptions. This deferred cost of products sold totaled \$167,000 as of December 31, 2006, compared to \$266,000 as of December 31, 2005, and was included in prepaid expenses and other current assets on Critical Therapeutics' balance sheet.

*Revenue under Collaboration Agreements.* Critical Therapeutics recognized collaboration revenues of \$6.4 million in 2006 compared to \$5.8 million in 2005. These revenues were primarily due to the portion of the \$12.5 million of initial fees MedImmune paid Critical Therapeutics that Critical Therapeutics recognized in each period, and the \$5.25 million cumulatively billed to MedImmune for milestone payments and development support from the inception of the agreement through December 31, 2006.

Through December 31, 2006, Critical Therapeutics billed a total of \$17.8 million under its agreement with MedImmune, consisting of the \$12.5 million initial payment, a \$1.3 million milestone payment and \$4.0 million of development support. Critical Therapeutics recognized \$17.5 million of these amounts as collaboration revenue through December 31, 2006. Critical Therapeutics reported the balance of the payments, totaling \$275,000, as deferred collaboration revenue and recognized such amount over the remaining estimated research term of its agreement with MedImmune based on the proportion of cumulative costs incurred as a percentage of the total costs estimated for the performance period. In 2006, Critical Therapeutics revised its cost estimate to reflect lower than expected costs to be incurred over the remainder of the contract with MedImmune. The change in estimate resulted in an increase in revenue recognized of approximately \$2.0 million in 2006. Critical Therapeutics recognized the balance in deferred revenue during 2007. As of December 31, 2006, Critical Therapeutics also had \$400,000 in deferred collaboration revenue under its collaboration agreement with Beckman Coulter, which it recognized as collaboration revenue in the first quarter of 2007.

*Costs and Expenses*

Effective January 1, 2006, Critical Therapeutics adopted the fair value recognition provisions of SFAS 123(R), using the modified prospective method, which allows it to recognize compensation cost for shares granted, but unvested, stock awards, new stock awards and stock awards modified, repurchased, or cancelled after

January 1, 2006. The discussion below is impacted by the fact that 2005 amounts do not include the impact of SFAS 123(R).

*Cost of Products Sold.* Cost of products sold in 2006 was \$2.2 million, compared to \$514,000 in 2005. Cost of products sold consisted primarily of the expenses associated with manufacturing and distributing ZYFLO and royalty payments to Abbott under the license agreement for ZYFLO. Cost of products sold included charges for inventory write-offs of \$299,000 during 2006, compared to \$280,000 during 2005. The write-offs resulted from excess or obsolete inventory that no longer can be used for commercial sale.

*Research and Development Expenses.* Research and development expenses in 2006 were \$26.9 million compared to \$30.0 million in 2005, a decrease of approximately \$3.0 million, or 10%. This decrease was primarily due to lower expenses associated with the technology transfer and manufacturing activities associated with ZYFLO and ZYFLO CR, as well as the reduction in the number of employees performing research and development functions following Critical Therapeutics' May and October 2006 restructurings. With the commercial launch of ZYFLO in October 2005, the costs of manufacturing ZYFLO were included in cost of products sold.

The following table summarizes the primary components of Critical Therapeutics' research and development expenses for the years ended December 31, 2006 and 2005:

	<b>Year Ended December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(In thousands)</b>	
Zileuton (ZYFLO and ZYFLO CR)	\$ 11,975	\$ 12,670
Zileuton injection	2,336	1,656
CTI-01	2,960	3,045
Alpha-7	3,903	2,434
HMGB1	1,829	2,030
General research and development expenses	2,600	7,260
Stock-based compensation expense	1,309	864
Total research and development expenses	\$ 26,912	\$ 29,959

The following summarizes the expenses associated with Critical Therapeutics' primary research and development programs:

*Zileuton (ZYFLO and ZYFLO CR).* During 2006, Critical Therapeutics incurred \$12.0 million in expenses related to its orally-dosed zileuton programs, including ZYFLO and ZYFLO CR, compared to \$12.7 million during 2005, a 5% decrease. This decrease was primarily due to the following:

lower manufacturing costs related to the product registration of ZYFLO, which was approved for commercial sale in September 2005; and

reduced costs related to clinical trials of zileuton in 2006 compared to 2005, when it conducted a Phase II clinical trial in patients with moderate to severe inflammatory acne.

The decreases were offset, in part, by the following:

completion of certain clinical trials related to the pharmacokinetic profile of ZYFLO CR in the bloodstream; and

initiation of the development of Critical Therapeutics R(+) isomer program for zileuton.

*Zileuton Injection.* During 2006, Critical Therapeutics incurred \$2.3 million in expenses related to its zileuton injection program, compared to \$1.7 million during 2005, a 41% increase. This increase was primarily due to the completion of a Phase I/II clinical trial of zileuton injection in 60 patients during 2006 as well as the costs to manufacture and supply the drug in support of that clinical trial. During 2005, Critical Therapeutics zileuton injection program was still in a preclinical stage of development

*CTI-01.* During 2006, Critical Therapeutics incurred \$3.0 million in expenses related to its CTI-01 program, which was comparable to the expenses incurred in 2005. The costs incurred in both 2006 and 2005 related primarily to the enrollment and conduct of a Phase II clinical trial of CTI-01 in patients undergoing major cardiac surgery including the use of a cardiopulmonary bypass machine. This clinical trial was initiated in 2005 and completed during 2006. Effective February 2007, Critical Therapeutics terminated its license agreement with the University of Pittsburgh related to the development of CTI-01 and its license agreement with Xanthus Pharmaceuticals related to the development of CTI-01.

*Alpha-7.* During 2006, Critical Therapeutics incurred \$3.9 million in expenses in connection with research and development of its alpha-7 program, compared to \$2.4 million during 2005, a 60% increase. The increase was primarily due to an increase in laboratory supplies and improved methods of allocating Critical Therapeutics research and development overhead expenses to its various programs, including the costs related to facilities, such as its laboratory space, and the depreciation expense on its laboratory equipment. In 2005, most of these expenses were included in Critical Therapeutics' general research and development expenses. The number of employees working on alpha-7 during 2006, as compared to 2005, was relatively consistent through most of the year leading up to Critical Therapeutics' October 2006 restructuring.

*HMGB1.* During 2006, Critical Therapeutics incurred \$1.8 million in expenses for its HMGB1 program, compared to \$2.0 million during 2005, a 10% decrease. This decrease was primarily due to lower license fees, sponsored research and laboratory supplies for continued testing under Critical Therapeutics' collaboration agreement with MedImmune as well as lower personnel costs devoted to this program. The decreased expenses were partially offset by increases related to the allocation of Critical Therapeutics' research and development overhead expenses to its various programs. These overhead expenses include the costs related to facilities, including Critical Therapeutics' laboratory space, and the depreciation expense on its laboratory equipment. In 2005, most of these expenses were included in Critical Therapeutics' general research and development expenses. In addition, Critical Therapeutics paid a \$250,000 milestone payment in 2005 to the licensor of HMGB1 for establishing preclinical proof-of-concept. The collaboration revenue recognized by Critical Therapeutics in 2006 for this program totaled \$6.4 million. The expenses for HMGB1 are reflected in the accompanying statements of operations as part of research and development expenses, while the funding received from MedImmune and Beckman Coulter to fund Critical Therapeutics' research efforts is included in revenue under collaboration agreements.

Critical Therapeutics' general research and development expenses, which are not allocated to any specific program, were \$2.6 million in 2006 compared to \$7.3 million in 2005, a decrease of 64%. This decrease was primarily due to improved methods of allocating Critical Therapeutics' research and development overhead expenses to its various programs, including costs related to personnel, laboratory and other facility costs. Unallocated facility and related costs were \$635,000 in 2006, compared to \$1.7 million in 2005. Unallocated depreciation expense declined to \$59,000 in 2006, compared to \$398,000 in 2005. The remaining general research and development expenses, which are incurred in support of all of Critical Therapeutics' research and development programs, are not easily allocable to any individual program, and therefore, have been included in general research and development expenses.

Stock-based compensation expense related to research and development increased by \$445,000 from \$864,000 in 2005 to \$1.3 million in 2006. The 2006 amount includes expenses for employee grants under SFAS 123(R) as well as grants made to non-employees who were primarily working on research and development activities. The adjustment to stock-based compensation expense for non-employees is calculated based on the change in fair value of Critical Therapeutics' common stock during the period. The increase in stock-based compensation expense is related primarily to Critical Therapeutics' adoption of SFAS 123(R), offset in part by the change in the market price of its common stock for unvested non-employee grants.





*Sales and Marketing Expenses.* Sales and marketing expenses for 2006 were \$18.3 million, compared to \$13.7 million for 2005. The \$4.6 million, or 34%, increase in 2006 was primarily attributable to the following:

an increase of approximately \$2.2 million in salary costs related to Critical Therapeutics' specialty sales force and its sales and customer management team, the majority of whom it hired in August 2005;

\$513,000 of additional stock-based compensation expense primarily related to its adoption of SFAS 123(R) and the increased number of employees during most of 2006;

higher infrastructure costs to support the sales force including leased vehicle, computer and software costs;

severance costs of \$302,000 and additional stock-based compensation expense of \$525,000 related to the departure of its former Senior Vice President of Sales and Marketing; and

higher product samples, promotional materials and other costs associated with ZYFLO that it incurred to support its sales effort.

In May and October 2006, Critical Therapeutics reduced the size of its sales and marketing efforts substantially to bring its cost structure more in-line with the expected future revenue for ZYFLO. In connection with these two restructurings, Critical Therapeutics reduced the size of its sales force promoting ZYFLO from approximately 80 sales representatives at the beginning of 2006 to 18 sales representatives at December 31, 2006. In addition, Critical Therapeutics reduced the size of the sales management team, its customer management, sales operations and marketing functions for similar reasons.

*General and Administrative Expenses.* General and administrative expenses for 2006 were \$13.5 million compared to \$11.4 million for 2005. The \$2.1 million, or 18%, increase in 2006 was primarily attributable to the following:

severance costs of \$670,000 and additional stock-based compensation expense of \$1.3 million related to the departure of Critical Therapeutics' former President and Chief Executive Officer Dr. Rubin; and

\$1.7 million of additional stock-based compensation expense primarily related to its adoption of SFAS 123(R).

These increases were offset, in part, by expenses related to Critical Therapeutics' June 2005 private placement, lower personnel costs related to its May and October 2006 restructurings and a reduction in expenses related to its compliance with the Sarbanes-Oxley Act.

*Restructuring Charges.* Restructuring charges totaled \$3.5 million in 2006 related to actions Critical Therapeutics took in May and October 2006. In May 2006, Critical Therapeutics recorded charges of \$499,000 for a restructuring of its operations that was intended to better align costs with revenue and operating expectations. In October 2006, Critical Therapeutics announced a second restructuring of its operations to focus its resources on the commercialization of ZYFLO CR and on the clinical development of zileuton injection and to significantly reduce its net cash expenditures through lower spending on its existing sales force as well as on its discovery and research programs. The restructuring charges for 2006 do not include approximately \$972,000 of severance expenses and \$1.8 million of stock-based compensation related to the departures of Critical Therapeutics' President and Chief Executive Officer and its Senior Vice President of Sales and Marketing. These amounts have been included in general and administrative expenses and sales and marketing expenses, as described above. At December 31, 2006, Critical Therapeutics had substantially completed the implementation of these restructurings and approximately \$212,000 of accrued restructuring costs remaining on its balance sheet was paid in 2007.

*Other*

*Other Income.* Interest income in 2006 was \$2.7 million, compared to \$2.4 million in 2005. The increase was primarily attributable to higher interest rates and higher cash and investment balances as a result of the financings that Critical Therapeutics completed in 2005 and 2006. Interest expense amounted to \$214,000 in

2006 and \$191,000 in 2005. The interest expense relates to borrowings under Critical Therapeutics loan with Silicon Valley Bank for capital expenditures.

## **Liquidity and Capital Resources**

### ***Sources of Liquidity***

Since its inception on July 14, 2000, Critical Therapeutics has raised proceeds to fund its operations through public offerings and private placements of equity securities, debt financings, the receipt of interest income, payments from its collaboration, license and co-promotion agreements, the exercise of stock options, and revenues from sales of ZYFLO and ZYFLO CR. As of March 31, 2008, Critical Therapeutics had \$20.5 million in cash, cash equivalents and investments. Critical Therapeutics has invested its cash and cash equivalents primarily in highly liquid, interest-bearing, investment grade securities in accordance with its established corporate investment policy.

In 2003, Critical Therapeutics entered into an exclusive license and collaboration agreement with MedImmune for the discovery and development of novel drugs for the treatment of acute and chronic inflammatory diseases associated with HMGB1, a newly discovered cytokine. Under this collaboration, MedImmune paid Critical Therapeutics initial fees of \$12.5 million and an additional \$5.4 million through March 31, 2008 for milestone payments and to fund certain research expenses incurred by Critical Therapeutics for the HMGB1 program. As of March 31, 2008, Critical Therapeutics had completed the research term of its agreement with MedImmune.

Under its collaboration with MedImmune, Critical Therapeutics may receive additional payments upon the achievement of research, development and commercialization milestones up to a maximum of \$124.0 million, after taking into account payments it is obligated to make to The Feinstein Institute on milestone payments it receives from MedImmune.

Under its co-promotion agreement with DEY, Critical Therapeutics received a non-refundable upfront payment of \$3.0 million in March 2007, a milestone payment of \$4.0 million in June 2007 following approval by the FDA of the NDA for ZYFLO CR in May 2007 and a milestone payment of \$5.0 million in December 2007 following commercial launch of ZYFLO CR.

*Credit Agreement with Silicon Valley Bank.* Critical Therapeutics has financed the purchase of general purpose computer equipment, office equipment, fixtures and furnishings, test and laboratory equipment, software licenses and the completion of leasehold improvements through advances under a credit agreement with Silicon Valley Bank, which was most recently modified as of January 6, 2006. As of March 31, 2008, Critical Therapeutics had repaid all outstanding debt owed to Silicon Valley Bank and had no borrowing capacity available under the modified credit agreement or any other credit agreement. Critical Therapeutics is currently considering financing alternatives to fund capital expenditures in the future.

### ***Funding Requirements***

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 \$10.8 million in the three months ended March 31, 2008 and \$4.7 million in the three months ended March 31, 2007. As of March 31, 2008, Critical Therapeutics had an accumulated deficit of approximately \$202 million. Critical Therapeutics expects that it will continue to incur substantial losses for the foreseeable future as it spends significant amounts to fund its research, development and commercialization efforts. As a result, there is substantial doubt about Critical Therapeutics ability to continue as a going concern. Critical Therapeutics ability to continue as a going concern will require it to obtain additional

financing to fund its operations. Critical Therapeutics has prepared its financial statements on the assumption that it will continue as a going concern, which contemplates the realization of assets and discharge of liabilities in the normal course of business. Doubt about Critical Therapeutics' ability to continue as a going concern may make it more difficult for Critical

Therapeutics to obtain financing for the continuation of its operations and could result in the loss of confidence by investors, creditors, suppliers and employees.

Critical Therapeutics expects to devote substantial resources to support the marketing of ZYFLO CR and ZYFLO and to fund the development of its product candidates. Critical Therapeutics has not made, and does not expect to make, a significant investment in capital expenditures in 2008. Critical Therapeutics expects to fund any capital expenditures through cash received from product sales and interest income from invested cash and cash equivalents and short-term investments. Critical Therapeutics' funding requirements will depend on numerous factors, including:

- the ongoing costs of the marketing of ZYFLO CR and ZYFLO;
- the scope, costs and results of its clinical trials of ZYFLO CR and zileuton injection;
- the amount and timing of sales and returns of ZYFLO CR and ZYFLO;
- the costs of ongoing sales, marketing and manufacturing activities for ZYFLO CR and ZYFLO;
- the time and costs involved in preparing, submitting, obtaining and maintaining regulatory approvals for its other product candidates;
- the timing, receipt and amount of milestone and other payments, if any, from DEY, MedImmune, Beckman Coulter, IMI or future collaborators or licensees;
- the timing, receipt and amount of sales and royalties, if any, from its product candidates;
- continued progress in its research and development programs, as well as the magnitude of these programs, including milestone payments to third parties under its 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;
- the 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 it may receive from its collaboration with MedImmune, sales of ZYFLO CR and ZYFLO represent Critical Therapeutics' only sources of cash flows and revenue. In addition to the foregoing factors, Critical Therapeutics believes that its ability to access external funds will depend upon market acceptance of ZYFLO CR and ZYFLO, 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 its ability to successfully commercialize ZYFLO CR and ZYFLO. Based on its operating plans, Critical Therapeutics believes that its available cash and cash equivalents and anticipated cash received from product sales will be sufficient

to fund anticipated levels of operations into the first quarter of 2009.

For the three months ended March 31, 2008, Critical Therapeutics' net cash used for operating activities was \$13.9 million and had minimal capital expenditures. If its existing resources are insufficient to satisfy its liquidity requirements or if it acquires or licenses rights to additional 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. In addition, the terms of the financing may adversely affect the holdings or the rights of Critical Therapeutics' stockholders. For example, if Critical Therapeutics raises additional funds by

issuing equity securities, further dilution to Critical Therapeutics then-existing stockholders will result. Such equity securities may have rights and preferences superior to those of the holders of Critical Therapeutics common stock. If Critical Therapeutics is unable to obtain funding on a timely basis, it 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. Critical Therapeutics also could be required to seek funds through arrangements with collaborators or others that may require it to relinquish rights to some of its technologies, product candidates or products, which it would otherwise pursue on its own.

### ***Contractual Obligations***

Critical Therapeutics has summarized in the table below its fixed contractual obligations as of March 31, 2008:

<b>Contractual Obligations</b>	<b>Total</b>	<b>Payments Due by Period</b>			
		<b>Less Than One Year</b>	<b>One to Three Years</b>	<b>Three to Five Years</b>	<b>More Than Five Years</b>
			<b>(In thousands)</b>		
Manufacturing and clinical trial agreements	\$ 19,810	\$ 12,304	\$ 7,104	\$ 402	\$
Research and license agreements	10,054	2,052	2,706	924	4,372
Marketing costs	7,344	2,094	5,250		
Lease obligations	434	434			
Consulting agreement and other	60	60			
<b>Total contractual cash obligations</b>	<b>\$ 37,702</b>	<b>\$ 16,944</b>	<b>\$ 15,060</b>	<b>\$ 1,326</b>	<b>\$ 4,372</b>

The amounts listed for manufacturing and clinical trial agreements represent amounts due to third parties for manufacturing, clinical trials and preclinical studies. On August 20, 2007, Critical Therapeutics entered into an agreement with Jagotec, under which Jagotec agreed to manufacture and supply bulk ZYFLO CR tablet cores for commercial sale. Critical Therapeutics has agreed to purchase minimum quantities of ZYFLO CR tablet cores during each 12-month period for the first five years following marketing approval of ZYFLO CR by the FDA. For the term of the contract, Critical Therapeutics has agreed to purchase specified amounts of its requirements for ZYFLO CR from Jagotec. The commercial manufacturing agreement has an initial term of five years beginning on May 22, 2007, and will automatically continue thereafter, unless Critical Therapeutics provides Jagotec with 24-months prior written notice of termination or Jagotec provides Critical Therapeutics with 36-months prior written notice of termination. In addition, Critical Therapeutics has the right to terminate the agreement upon 30-days prior written notice in the event any governmental agency takes any action, or raises any objection, that prevents Critical Therapeutics from importing, exporting or selling ZYFLO CR. Critical Therapeutics also may terminate the agreement upon six-months advance notice in the event that an AB-rated generic pharmaceutical product containing zileuton is introduced in the United States and it determines to permanently cease commercialization of ZYFLO CR. Likewise, Critical Therapeutics may terminate the agreement upon 12-months advance notice if it intends to discontinue commercializing ZYFLO CR tablets. Furthermore, each party has the right to terminate the agreement upon the occurrence of a material uncured breach by the other party. In the event either party terminates the agreement, Critical Therapeutics has agreed to purchase quantities of ZYFLO CR tablets that are subject to binding forecasts.

In addition, Critical Therapeutics entered into a manufacturing and supply agreement with Rhodia Pharma Solutions Ltd. for commercial production of zileuton API, subject to specified limitations, through December 31, 2009. On September 30, 2006, Rhodia SA sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhodia SA assigned Critical Therapeutics' contract with Rhodia Pharma Solutions Ltd. to Shasun. Under this agreement, Critical Therapeutics committed to purchase a minimum amount of API in the fourth quarter of 2006, the first quarter of 2007 and the first quarter of 2008. In addition, Critical Therapeutics has agreed to purchase specified quantities of API in 2008 and 2009 with a portion subject to the right of cancellation with a termination fee. The API purchased from Shasun currently has a minimum shelf-life of 36 months.



The amounts listed for research and license agreements represent Critical Therapeutics' fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that Critical Therapeutics may be required to pay under its license agreements upon the achievement of scientific, regulatory and commercial milestones that may become payable depending on the progress of scientific development and regulatory approvals, including milestones such as the submission of an IND to the FDA, similar submissions to foreign regulatory authorities and the first commercial sale of Critical Therapeutics' products in various countries.

Critical Therapeutics is party to a number of agreements that require it to make milestone payments. In particular, under Critical Therapeutics' license agreement with Abbott Laboratories for zileuton, Critical Therapeutics agreed to make aggregate milestone payments of up to \$13.0 million to Abbott upon the achievement of various development and commercialization milestones relating to zileuton, including the completion of the technology transfer from Abbott to it, filing and approval of a product in the United States and specified minimum net sales of licensed products. Through March 31, 2008, Critical Therapeutics has made aggregate milestone payments of \$7.8 million to Abbott under its license agreements related to ZYFLO and ZYFLO CR. In addition, under its license agreement with Jagotec, through its subsidiary Jagotec, for ZYFLO CR, Critical Therapeutics agreed to make aggregate milestone payments of up to \$6.6 million upon the achievement of various development and commercialization milestones. Through March 31, 2008, Critical Therapeutics has made aggregate milestone payments of \$3.0 million to Jagotec under this agreement. In May 2007, Critical Therapeutics received FDA approval of the NDA for ZYFLO CR. Included in the amounts listed for research and license agreements are the combined first and second anniversary milestone payments for the FDA's approval of ZYFLO CR due to Abbott and Jagotec totaling \$3.8 million.

The amounts listed for marketing costs represent advertising and promotional commitments under Critical Therapeutics' co-promotion agreement with DEY related to Critical Therapeutics' marketing support for ZYFLO CR.

The amounts listed for lease obligations represent the amount Critical Therapeutics owes under its facility, computer and vehicle lease agreements under both operating and capital leases.

The amounts listed for consulting agreements are for fixed payments due to Critical Therapeutics' scientific and business consultants.

The amounts shown in the table do not include royalties on net sales of Critical Therapeutics' products and payments on sublicense income that it may owe as a result of receiving payments under its collaboration or license agreements.

The amounts listed for research and license agreements, consulting agreements and manufacturing and clinical trial agreements include amounts that Critical Therapeutics owes under agreements that are subject to cancellation or termination by it under various circumstances, including a material uncured breach by the other party, minimum notice to the other party or payment of a termination fee.

The amounts listed in the table above do not include payment of a termination fee of \$1.0 million or the reimbursement of expenses of up to \$150,000 that Critical Therapeutics could be obligated to pay to Cornerstone in specified circumstances in connection with the termination of the merger agreement with Cornerstone.

Critical Therapeutics evaluates the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, Critical Therapeutics is required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. While Critical Therapeutics' purchase commitment for API from Shasun exceeds its current forecasted demand in 2008, Critical Therapeutics expects that any excess API purchased in 2007, 2008 and 2009 under its agreement with Shasun will be used in commercial production batches in 2008, 2009 and 2010 and sold before it

requires retesting. Therefore, no reserve for this purchase commitment has been recorded as of March 31, 2008.

At March 31, 2008, Critical Therapeutics had \$9.7 million in inventory. Critical Therapeutics expects that its inventory levels in the second and third quarters of 2008 will decrease as it has no API purchase commitments in those periods. Significant differences between Critical Therapeutics' current estimates and judgments and future estimated demand for its products and the useful life of inventory may result in significant charges for excess inventory or purchase commitments in the future. These differences could have a material adverse effect on Critical Therapeutics' financial condition and results of operations during the period in which Critical Therapeutics recognizes charges for excess inventory. For example, Critical Therapeutics recorded charges of \$821,000 in 2007 and \$299,000 in 2006 to reserve for excess or obsolete inventory that had an expiration date such that the product was unlikely to be sold. In addition, in the first quarter of 2008, four additional batches of ZYFLO CR tablets did not meet Critical Therapeutics' product release specifications and could not be released into Critical Therapeutics' commercial supply chain. Critical Therapeutics has initiated an investigation to determine the cause of this issue, but the investigation is ongoing and not yet complete. Critical Therapeutics is currently unable to accurately assess the timing and quantity of future batches of ZYFLO CR that may be released for commercial supply. However, the Critical Therapeutics anticipates that, as a result of the timing of the investigation, it will need to reserve for additional inventory that is unlikely to be sold. These charges were included in cost of products sold in the statements of operations for these periods.

Currently, Critical Therapeutics purchases its API for commercial requirements for ZYFLO and ZYFLO CR from a single source. In addition, Critical Therapeutics currently contracts with a single third party for the manufacture of uncoated ZYFLO CR tablets and with another single third party for the coating and packaging of these tablets. The disruption or termination of the supply of API, a significant increase in the cost of the API from this single source or the disruption or termination of the manufacturing of Critical Therapeutics' commercial products could have a material adverse effect on Critical Therapeutics' business, financial position and results of operations.

### **Effects of Inflation**

Critical Therapeutics' assets are primarily monetary, consisting primarily of cash, cash equivalents and investments. Because of their liquidity, these assets are not significantly affected by inflation. Critical Therapeutics also believes that it has intangible assets in the value of its technology. In accordance with generally accepted accounting principles, Critical Therapeutics has not capitalized the value of this intellectual property on its consolidated balance sheet. Because Critical Therapeutics intends to retain and continue to use its equipment, furniture and fixtures and leasehold improvements, Critical Therapeutics believes that the incremental inflation related to the replacement costs of such items will not materially affect its operations. However, the rate of inflation affects Critical Therapeutics' expenses, such as those for employee compensation and contract services, which could increase its level of expenses and the rate at which it uses its resources.

### **Recent Accounting Pronouncements**

In November 2007, the FASB, Emerging Issues Task Force, or EITF, issued No. EITF Issue 07-01, *Accounting for Collaborative Arrangements*, or EITF 07-01. EITF 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from or made to other collaborators based on other applicable generally accepted accounting principles or, in the absence of other applicable generally accepted accounting principles, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. Further, EITF 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer or analogous relationship subject to EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer*. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. Critical Therapeutics does not expect the adoption of EITF 07-01 to have a material impact on its financial statements and results of operations.

In June 2007, the EITF issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 concludes that non-refundable advance payments for future research and development activities should be

deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The initial adjustment to reflect the effect of applying this EITF as a change in accounting principle would be accounted for as a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. The adoption of EITF 07-03 did not have a material impact on Critical Therapeutics' financial statements and results of operations.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, or SFAS 141(R). SFAS 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values and changes other practices under SFAS No. 141, *Business Combinations*, some of which could have a material impact on how an entity accounts for its business combinations. SFAS 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008 and is applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009. The provisions of SFAS 141(R) will only impact Critical Therapeutics if it is a party to a business combination after the pronouncement has been adopted.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interest in Consolidated Financial Statements - an amendment of ARB No. 51*, or SFAS 160. SFAS 160 requires entities to report non-controlling minority interests in subsidiaries as equity in consolidated financial statements. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. SFAS 160 is applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for presentation and disclosure requirements, which are applied retrospectively for all periods presented. Critical Therapeutics does not expect the adoption of SFAS 160 to have a material impact on its financial statements and results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of SFAS 115*, or SFAS 159. SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which a company has chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Critical Therapeutics was required to adopt SFAS 159 on January 1, 2008. The adoption of SFAS 159 did not have a material impact on Critical Therapeutics' financial statements and results of operations, as it elected not to measure any financial assets or liabilities at fair value.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. In February 2008, the FASB issued Staff Position No. FAS 157-2, or FSP 157-2, that defers the effective date of applying the provisions of SFAS 157 to the fair value measurement of nonfinancial assets and nonfinancial liabilities until fiscal years beginning after November 15, 2008. Critical Therapeutics was required to adopt the provisions of SFAS 157 that pertain to financial assets and liabilities on January 1, 2008. Critical Therapeutics is currently evaluating the effect FSP 157-2 will have on its financial statements and results of operations.

**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT  
CRITICAL THERAPEUTICS MARKET RISK**

Critical Therapeutics is exposed to market risk related to changes in interest rates. Critical Therapeutics' current investment policy is to maintain an investment portfolio consisting of U.S. government treasury and agency notes, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, directly or through managed funds, with maturities of two years or less. Critical Therapeutics' cash is deposited in and invested through highly rated financial institutions in North America. Critical Therapeutics' investments are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10% from levels at March 31, 2008, Critical Therapeutics estimates that the fair value of Critical Therapeutics' investment portfolio would decline by approximately \$1,000. Critical Therapeutics could be exposed to losses related to these securities should one of Critical Therapeutics' counterparties default. Critical Therapeutics attempts to mitigate this risk through credit monitoring procedures. Critical Therapeutics has the ability to hold its fixed income investments until maturity, and therefore Critical Therapeutics would not expect its operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on Critical Therapeutics' investments. At March 31, 2008, Critical Therapeutics held approximately \$287,000 in auction rate securities with a AAA credit rating upon purchase. In February 2008, Critical Therapeutics was informed that there was insufficient demand at auction for these securities. As a result, this amount is currently not liquid and may not become liquid unless the issuer is able to refinance it. Critical Therapeutics has classified its investment in auction rate securities as a long-term investment and included the investment in other assets on Critical Therapeutics' balance sheet.

## **CORNERSTONE'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

You should read the following discussion and analysis of Cornerstone's financial condition and results of operations together with the Selected Historical Consolidated Financial Data of Cornerstone section of this proxy statement/prospectus and Cornerstone's financial statements and accompanying notes included in this proxy statement/prospectus. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Cornerstone's actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including, but not limited to, those set forth in the Risks Related to Cornerstone section of this proxy statement/prospectus.

### **Overview**

Cornerstone is a specialty pharmaceutical company focused on acquiring, developing and commercializing prescription products for the respiratory market. 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.

Since its inception in 2004, Cornerstone has acquired the rights to eight marketed product lines. Cornerstone began to market its first product in 2004. As of June 30, 2008, Cornerstone promoted two product lines with 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 revenues from product sales and royalties from the sale of six marketed product lines that include products that it does not promote. Two of these six product lines are promoted by third parties, and the remaining four are not promoted by Cornerstone or any third party.

### ***Key Marketed Products***

Cornerstone currently promotes SPECTRACEF and the ALLERX Dose Pack family of products. In addition, Cornerstone has entered into co-promotion agreements with SJ Pharmaceuticals for the co-promotion of these products. Under these agreements, Cornerstone pays royalties to SJ Pharmaceuticals equal to a percentage of the net profits on Cornerstone's sales of these products above a specified baseline based on prescriptions by assigned, targeted prescribers within assigned sales territories.

***SPECTRACEF.*** SPECTRACEF is a third generation cephalosporin with the API cefditoren pivoxil. SPECTRACEF is indicated for the treatment of mild to moderate infections caused by pathogens associated with particular respiratory tract infections. In October 2006, Cornerstone acquired from Meiji the exclusive U.S. rights to manufacture and sell SPECTRACEF and additional cefditoren pivoxil products and to use the SPECTRACEF trademark from Meiji pursuant to a license and supply agreement, as amended and supplemented. In exchange for these exclusive U.S. rights, Cornerstone agreed to pay Meiji a \$6.0 million non-refundable license fee in installments over five years and quarterly royalties based on the net sales of the cefditoren pivoxil products covered by the agreement. Cornerstone paid \$250,000 of the license fee in 2006 and \$1.0 million in 2007. Additional installments of the license fee are due and payable as follows: \$1.0 million in October 2008, \$1.0 million in October 2009, \$1.25 million in October 2010 and \$1.5 million in October 2011. Cornerstone is also required to purchase annual minimum quantities of cefditoren pivoxil from Meiji during the first five years of the agreement.

***ALLERX Dose Pack Products.*** Cornerstone currently markets three ALLERX Dose Pack products, each in 10-day and 30-day regimens:

ALLERX 10 Dose Pack and ALLERX 30 Dose Pack, both of which Cornerstone began marketing in February 2008;

ALLERX Dose Pack DF and ALLERX Dose Pack DF 30, which Cornerstone began marketing in August 2006 and July 2007, respectively; and



ALLERX Dose Pack PE and ALLERX Dose Pack PE 30, which Cornerstone began marketing in September 2006 and October 2007, respectively.

Each of these products is administered orally and is indicated for the temporary relief of symptoms associated with allergic rhinitis. In February 2005, Cornerstone acquired all of the rights to the ALLERX products held by Adams in exchange for Cornerstone's rights to the Humibid family of products. Cornerstone began marketing the first of its ALLERX Dose Pack products in February 2005, which it has replaced with ALLERX 10 Dose Pack and ALLERX 30 Dose Pack. Cornerstone believes that ALLERX 10 Dose Pack, ALLERX 30 Dose Pack, ALLERX Dose Pack PE and ALLERX Dose Pack PE 30 are protected under claims in U.S. Patent number 6,843,372, or the 372 Patent, which Cornerstone licensed directly from Pharmaceutical Innovations, in August 2006. Under its license agreement with Pharmaceutical Innovations, as amended, Cornerstone pays Pharmaceutical Innovations royalties based on a percentage of the net sales per calendar year of each product, subject to specified minimums.

### *Other Products*

Cornerstone has acquired or licensed the rights to six marketed product lines that it does not actively promote. Two of these six product lines are promoted by third parties, and the remaining four are not currently promoted by Cornerstone or any third party. Cornerstone's other products that have generated the most net revenues to date are BALACET 325, APAP 500 and DECONSAL products.

*BALACET 325 and APAP 500.* Both BALACET 325 and APAP 500 are indicated for the relief of mild to moderate pain. In July 2004, Cornerstone licensed the rights to these products from Vintage for an upfront payment of \$5.0 million, a note payable of \$3.0 million and ongoing quarterly royalty payments equal to a percentage of the products' net sales. Cornerstone paid the note payable in full in February 2006. Cornerstone began marketing BALACET 325 in April 2005, but ceased all marketing efforts for this product in January 2007 to concentrate its resources on the respiratory market.

In September 2005, Cornerstone entered into a supply and marketing agreement with Pliva relating to APAP 500. Under this agreement, Pliva sells APAP 500 that is supplied to it by Vintage and pays Cornerstone royalties based on the quarterly net sales of APAP 500. Cornerstone's agreement with Pliva will terminate on December 31, 2008, at which time Cornerstone expects that one of its subsidiaries, Aristos Pharmaceuticals, Inc., or Aristos, will begin marketing APAP 500. Cornerstone formed Aristos to market generic products, including APAP 500; launch authorized generic versions of Cornerstone's products that become subject to generic competition; and acquire or in-license generic versions of products with little or no generic competition that Cornerstone's management believes offer attractive returns on investment, regardless of whether such products are used to treat respiratory ailments.

In April 2007, Cornerstone entered into a co-promotion agreement with Atley Pharmaceuticals to co-promote BALACET 325. Under the agreement, Cornerstone pays Atley Pharmaceuticals co-promotion fees based on a percentage of the net profits from Cornerstone's sales above a specified baseline based on prescriptions by all prescribers within assigned sales territories.

*DECONSAL.* In July 2004, Cornerstone acquired all rights related to prescription products marketed under the DECONSAL brand name from Carolina Pharmaceuticals in exchange for quarterly royalties equal to a percentage of the net sales of DECONSAL products through December 31, 2006. In January 2005, Cornerstone launched DECONSAL II, an expectorant and nasal decongestant combination tablet for oral administration with the APIs guaifenesin and phenylephrine. In 2006, Cornerstone launched the DECONSAL CT Tannate Chewable Tablets and DECONSAL DM Tannate Chewable Tablets, which contain an antihistamine, a nasal decongestant and, with respect to DECONSAL DM, an antitussive. In May 2007, the FDA announced that manufacturers must stop making products

that contain guaifenesin in a timed release dosage form by August 27, 2007 and stop shipping in interstate commerce by November 25, 2007. As a result, Cornerstone stopped selling DECONSAL II in November 2007.

*EXTENDRYL*. In January 2005, Cornerstone acquired the *EXTENDRYL* family of respiratory medication products through a sublicense agreement with Tryon Laboratories, Inc. These prescription products are

indicated for the relief of respiratory congestion, allergic rhinitis and vasomotor rhinitis. Cornerstone's sales force promoted the EXTENDRYL products until May 2005. At that time, Cornerstone granted Auriga an exclusive sublicense to market the EXTENDRYL products in exchange for royalties on Auriga's net sales of EXTENDRYL. Auriga and Cornerstone amended the license agreement in September 2006 to include EXTENDRYL line extensions and lower the royalty rate owed to Cornerstone in exchange for the issuance of 200,000 shares of Auriga common stock to Cornerstone.

**HYOMAX.** In May 2008, Cornerstone acquired the exclusive rights to the HYOMAX line of products through a supply and marketing agreement with Sovereign. Under this agreement, Cornerstone is obligated to use commercially reasonable efforts to market the HYOMAX line of products to wholesalers and distributors in the United States in exchange for a 50% share of the net profits realized from the sale of the products. HYOMAX is a product line comprised of generic formulations of three antispasmodic medications containing the API hyoscyamine sulfate, an anticholinergic, which may be prescribed for various gastrointestinal disorders. Aristos launched the first HYOMAX product, HYOMAX SL 0.125 mg tablets, in May 2008, followed by HYOMAX SR 0.375 mg tablets and HYOMAX FT 0.125 mg chewable melt tablets in June 2008.

#### *Product Candidates*

Cornerstone's product development pipeline includes three SPECTRACEF line extensions, a methscopolamine and antihistamine combination product candidate and two hydrocodone cough suppressant candidates. The SPECTRACEF line extensions include:

SPECTRACEF 400 mg, a single 400 mg tablet, twice-daily dosage of SPECTRACEF, for which Cornerstone has submitted an sNDA to the FDA;

SPECTRACEF Once Daily, a single tablet, once-daily dosage of SPECTRACEF, for which Cornerstone expects to commence clinical trials in the fourth quarter of 2008 and additional clinical trials in 2009, with an NDA submission targeted for 2010; and

SPECTRACEF Suspension, an oral, liquid suspension of SPECTRACEF, for which Cornerstone expects to submit an NDA in 2009 for use of this product candidate by children with pharyngitis or tonsillitis and expects to conduct additional clinical trials in 2009 regarding acute otitis media and submit an sNDA for this indication in 2010.

Cornerstone is developing the methscopolamine and antihistamine combination product candidate for the treatment of the symptoms of allergic rhinitis. Cornerstone has filed an IND for this product candidate and plans to commence clinical trials in the fourth quarter of 2008, with an NDA submission targeted for 2010. The hydrocodone cough suppressant product candidates are extended-release antihistamine and antitussive, or cough suppressant, combination products, for which Cornerstone plans to submit applications for marketing approval in the first quarter of 2009 and, if approved, to commercially launch these product candidates in the fourth quarter of 2009.

#### *Collaboration Agreement Revenues*

In January 2005, Cornerstone entered into a co-promotion agreement with Lupin Pharmaceuticals. Under this agreement, Cornerstone agreed to co-promote Lupin Pharmaceuticals' Suprax, an oral suspension of cefixime, an anti-infective, in exchange for the payment to Cornerstone of co-promotion fees based on a percentage of specified levels of net sales. Cornerstone earned approximately \$1.1 million in co-promotion revenue from Lupin Pharmaceuticals for co-promoting Suprax in 2005. In May 2005, Cornerstone and Lupin Ltd. entered into a collaboration and license agreement for the development and commercialization of additional products. Under the

terms of the agreement, Cornerstone and Lupin Ltd. agreed to share development costs, and Cornerstone agreed to make upfront and milestone payments to Lupin and issued a warrant to purchase 1,746,405 shares of its common stock to Lupin Ltd. In February 2006, Lupin Pharmaceuticals notified Cornerstone that it had terminated the co-promotion agreement due to Cornerstone's failure to meet certain requirements under the agreement. In December 2006, Lupin Pharmaceuticals and Lupin Ltd. entered into a settlement agreement providing, among other things, for the cancellation of the warrant held by Lupin Ltd.

that was exercisable for shares of Cornerstone's common stock, for Cornerstone to release all of its interests in Suprax and for Cornerstone to pay Lupin Ltd. \$1.25 million. The collaboration and license agreement was terminated in December 2006.

### ***History of Losses***

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 approximately \$669,000 in the quarter ended March 31, 2008 and \$570,000 in the year ended December 31, 2007. As of March 31, 2008, Cornerstone's accumulated deficit was \$12.4 million. Cornerstone expects to continue to incur significant development and commercialization expenses as it seeks FDA approval for 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 team 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. Accordingly, Cornerstone will need to increase its revenues to be able to sustain and increase its profitability. There is no assurance that Cornerstone will be able to do so.

### **Financial Operations Overview**

#### ***Net Revenues***

Cornerstone's net revenues are comprised of net product sales, royalty agreement revenues and co-promotion fees. Cornerstone recognizes product sales net of estimated allowances for product returns; estimated rebates in connection with contracts relating to managed care, Medicaid and Medicare; estimated chargebacks; price adjustments; product vouchers; co-pay vouchers; and prompt payment and other discounts. The primary factors that determine Cornerstone's net product sales are the level of demand for Cornerstone's products, unit sales prices and the amount of sales adjustments that Cornerstone recognizes. Royalty agreement revenues consist of royalties Cornerstone receives under license agreements with third parties that sell products to which Cornerstone has rights. The primary factors that affect royalty agreement revenues are the demand and sales prices for such products and the royalty rates that Cornerstone receives on the sales of such products by third parties. Co-promotion fees include royalties Cornerstone earned in 2005 under its co-promotion agreement with Lupin Pharmaceuticals.

Since Cornerstone's inception in March 2004, approximately 93% of Cornerstone's net revenues have been from product sales, including sales of Cornerstone's ALLERX Dose Pack family of products, SPECTRACEF, BALACET 325 and its DECONSAL products.

The following table sets forth a summary of Cornerstone's net revenues for the years ended December 31, 2007, 2006 and 2005 and for the three months ended March 31, 2008 and 2007.

	Year Ended December 31,			Three Months Ended March 31,	
	2007	2006	2005	2008	2007
	(In thousands)				
<i>Net Product Sales</i>					
ALLERX 10 Dose Pack/ALLERX 30 Dose Pack(1)	\$ 11,103	\$ 11,349	\$ 10,141	\$ 3,067	\$ 6,228
ALLERX Dose Pack DF/ALLERX Dose Pack DF 30	967	1,807		1,167	94
ALLERX Dose Pack PE/ALLERX Dose Pack PE 30	1,439	1,342		2,099	141
SPECTRACEF	6,886	271		182	763
BALACET 325	4,403	2,943	1,667	2,145	747
DECONSAL CT and DECONSAL DM	99	1,146		141	43
Other currently marketed products	671	474	897	200	203
Discontinued products	679	1,107	2,913		(3)
<b>Total Net Product Sales</b>	<b>26,247</b>	<b>20,439</b>	<b>15,618</b>	<b>9,001</b>	<b>8,216</b>
<i>Royalty Agreement Revenues</i>	1,824	1,678	753	444	472
<i>Collaboration Agreement Revenues</i>			1,099		
<b>Net Revenues</b>	<b>\$ 28,071</b>	<b>\$ 22,117</b>	<b>\$ 17,470</b>	<b>\$ 9,445</b>	<b>\$ 8,688</b>

(1) Net product sales amounts for ALLERX 10 Dose Pack/ALLERX 30 Dose Pack include net product sales of the ALLERX Dose Pack product prior to its reformulation as ALLERX 10 Dose Pack/ALLERX 30 Dose Pack in February 2008.

From time to time and, typically, at least once per year, Cornerstone implements price increases on both its promoted and non-promoted products.

### ***Cost of Product Sales***

Cornerstone's cost of product sales is primarily comprised of the costs of manufacturing and distributing Cornerstone's pharmaceutical products. In particular, cost of product sales includes third-party manufacturing and distribution costs, the cost of active pharmaceutical ingredients, freight and shipping, reserves for excess or obsolete inventory and labor, benefits and related employee expenses for personnel involved with overseeing the activities of Cornerstone's third-party manufacturers.

Cornerstone contracts with third parties to manufacture all of its products and product candidates. Changes in the price of raw materials and manufacturing costs could adversely affect Cornerstone's gross margins on the sale of its products. Changes in Cornerstone's mix of products sold also affect its cost of product sales. Accordingly, Cornerstone's management expects gross margins will change as its product mix is altered by the launch of new products.

***Sales and Marketing Expenses***

Cornerstone's sales and marketing expenses consist of labor, benefits and related employee expenses for personnel in its sales, marketing and sales operations functions; advertising and promotion costs, including the costs of samples; and the fees it pays under its co-promotion agreements to third parties to promote its products, which are based on a percentage of net profits from product sales, determined in accordance with the particular agreement. The most significant component of Cornerstone's sales and marketing expenses is labor, benefits and related employee expenses for its sales personnel.

In August 2004, shortly after its inception, Cornerstone hired its first national sales director and its first four sales managers, followed by its first class of 25 sales representatives in January 2005. By December 31, 2005, Cornerstone had grown its sales team to 74 sales professionals. In January 2006, however, Cornerstone reduced the size of its sales team to 30 sales professionals as part of a reduction in force. Cornerstone implemented its January 2006 reduction in force in connection with ceasing development of a product candidate with the API cephalexin.

From January 2007 through August 2007, Cornerstone increased the size of its sales team to 40 sales professionals. In September 2007, Cornerstone added a commission-based sales team to complement its pre-existing sales team, which continued to be compensated with salaries, bonuses and related benefits. The addition of the commission-based sales team included the hiring of 72 sales professionals, including a second national sales director, who was hired as a consultant. As of December 31, 2007, Cornerstone's total sales team consisted of 109 sales professionals.

During the first part of 2008, through attrition and otherwise, the number of Cornerstone's sales professionals declined to 93 as of April 30, 2008. On May 1, 2008, Cornerstone consolidated all of its sales functions under one national sales director, reduced the size of its sales team to 59 sales professionals and eliminated commission-based compensation for the previous members of its commission-based sales team. Following the reduction in force, Cornerstone began compensating all of its sales professionals with salaries, bonuses and related benefits.

Cornerstone expects that its sales and marketing expenses will increase as it expands its sales and marketing infrastructure to support additional products and product lines and as a result of increased co-promotion fees due to greater product sales.

#### ***Royalty Expenses***

Royalty expenses include the contractual amounts Cornerstone is required to pay the licensors from which it has acquired the rights to its marketed products. Royalties are generally based on a percentage of the products' net sales. With respect to the HYOMAX line of products, royalties are based on a percentage of the net profits earned by Cornerstone on the sale of the products. Additionally, as described in the section entitled "Cornerstone's Business Legal Proceedings" of this proxy statement/prospectus, Cornerstone has been engaged in litigation with several companies that Cornerstone believes have infringed the '796 Patent by marketing pharmaceutical products intended as generic equivalents of the former formulation of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack. In connection with the settlement of such litigation, Cornerstone sometimes has agreed to pay royalties with respect to future sales of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack, including their former formulation and any new formulations. Cornerstone has agreed to pay these royalties in exchange for the other party agreeing to withdraw its challenges to the validity of the '796 Patent and to cease marketing products that compete with the ALLERX Dose Pack family of products. Any such payments pursuant to a settlement agreement are also included in royalty expenses. Although product mix affects Cornerstone's royalties, Cornerstone generally expects that its royalty expenses will increase as total net product sales increase.

#### ***General and Administrative Expenses***

General and administrative expenses primarily include labor, benefits and related employee expenses for personnel in executive, finance, accounting, business development, information technology, regulatory/medical affairs and human resource functions. Other costs include facility costs not otherwise included in sales and marketing or research and development expenses and professional fees for legal and accounting services. General and administrative expenses also consist of the costs of maintaining and overseeing Cornerstone's intellectual property portfolio, which include the cost of external legal counsel and the mandatory fees of the U.S. Patent and Trademark Office. Beginning in December 2006, Cornerstone has recorded the expenses of its Aristos subsidiary in general and administrative expenses. Cornerstone expects that general and administrative expenses will increase as it continues to build the



infrastructure necessary to support its commercialization and research and development activities and meeting its compliance obligations as a public company. In addition,

Cornerstone has incurred, and expects to continue to incur, additional legal, accounting and related costs relating to its proposed merger with Critical Therapeutics.

### *Research and Development Expenses*

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of labor, benefits and related employee expenses for personnel, fees paid to professional service providers for monitoring and analyzing clinical trials, expenses incurred under joint development agreements, regulatory costs, costs of contract research and manufacturing and the cost of facilities used by Cornerstone's research and development personnel. Cornerstone expenses research and development costs as incurred. Cornerstone believes that significant investment in research and development is important to its competitive position and plans to increase its expenditures for research and development to realize the potential of the product candidates that it is developing or may develop.

The following table summarizes Cornerstone's research and development expenses for each of the years ended December 31, 2007, 2006 and 2005 and the three months ended March 31, 2008 and 2007. The expenses summarized in the following table reflect costs directly attributable to product candidates currently in development and to product candidates for which Cornerstone has discontinued development. Additionally, research and development expenses include Cornerstone's costs of qualifying new cGMP third-party manufacturers for its products, including expenses associated with any related technology transfer. Cornerstone does not allocate salaries, benefits or other indirect costs to the research and development expenses associated with individual product candidates. Rather, Cornerstone includes these costs in general and administrative expenses.

	<b>Three Months Ended March 31,</b>		<b>Year Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands)</b>		<b>(In thousands)</b>		
<i>In development:</i>					
SPECTRACEF 400 mg	\$ 29		\$ 383		
SPECTRACEF Once Daily	26				
SPECTRACEF Qualification of Backup Manufacturer		5	90		
Methscopolamine/Antihistamine Product Candidate (CBP 058)	37				
ALLERX	6		402	231	
DECONSAL				10	
Generic Product Development			73		
<i>Discontinued development:</i>					
Cephalexin				8	266
<b>Total</b>	<b>\$ 98</b>	<b>\$ 5</b>	<b>\$ 948</b>	<b>\$ 249</b>	<b>\$ 266</b>

Research and development expenses for SPECTRACEF 400 mg of \$29,000 in the first quarter of 2008 and of \$383,000 in 2007 are related to formulation work, a bioequivalence study, the sNDA submission for SPECTRACEF 400 mg and related consulting costs.

Research and development expenses for ALLERX of \$6,000 in the first quarter of 2008 consist of costs incurred for ALLERX NDA studies and validation studies for the qualification of new facilities to manufacture bulk tablets for the ALLERX product line. Research and development expenses for ALLERX were \$402,000 in 2007 and were incurred for validation studies and manufacturing methodology and technology transfer in connection with a change in Cornerstone's third-party manufacturing site used to produce bulk tablets for the ALLERX product line. Research and development expenses for ALLERX were \$231,000 in 2006 and were incurred for life cycle product development of the ALLERX family of products.

### ***Amortization and Depreciation Expenses***

Cornerstone capitalizes its costs to license product rights from third parties as such costs are incurred and amortizes these amounts on a straight-line basis over the estimated useful life of the product or the remaining trademark or patent life, whichever is shorter. Cornerstone reevaluates the useful life of its products on an annual basis to determine whether the value of its product rights assets have been impaired and appropriately adjusts amortization to account for such impairment. Amortization and depreciation expense also includes depreciation expense for Cornerstone's property and equipment, which it depreciates over the estimated useful lives of the assets using the straight-line method. Amortization and depreciation expenses are expected to increase in the future as Cornerstone begins amortizing product rights related to new products.

### ***Other Charges***

Other charges include miscellaneous expenses related to settlements of litigation, costs incurred in 2006 related to a merger that was not consummated and Cornerstone's forfeiture of product rights to market Suprax in connection with the termination in 2006 of its co-promotion agreement with Lupin Pharmaceuticals.

### ***Basis of Presentation***

Cornerstone's consolidated financial statements include the accounts of Cornerstone BioPharma Holdings, Inc. and its wholly owned subsidiaries Cornerstone BioPharma, Inc., Cornerstone Biopharma, Ltd., and Aristos.

### ***Critical Accounting Estimates***

Management's discussion and analysis of Cornerstone's financial condition and results of operations are based on Cornerstone's consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of its financial statements requires Cornerstone's management to make estimates and assumptions that affect Cornerstone's reported assets and liabilities, revenues and expenses and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, Cornerstone's reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

Cornerstone regards an accounting estimate or assumption underlying its financial statements as a critical accounting estimate where:

the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

the impact of the estimates and assumptions on its financial condition or operating performance is material.

Cornerstone's significant accounting policies are described in the notes to Cornerstone's consolidated financial statements appearing elsewhere in this proxy statement/prospectus. Not all of these significant accounting policies, however, fit the definition of critical accounting estimates. Cornerstone believes that its estimates relating to revenue recognition, product rights, inventory, accrued expenses and stock-based compensation described below fit the definition of critical accounting estimates.

### ***Revenue Recognition***

*Product Sales.* Cornerstone recognizes revenue from its product sales in accordance with SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, and SFAS 48, upon transfer of title, which occurs when product is received by its customers. Cornerstone sells its products primarily to pharmaceutical wholesalers, distributors and pharmacies, which have the right to return the products they purchase. Under SFAS 48, Cornerstone is required to reasonably estimate the amount of future returns at the time of revenue recognition. Cornerstone recognizes product sales net of estimated allowances for product returns; estimated rebates in

connection with contracts relating to managed care, Medicaid and Medicare; estimated chargebacks; price adjustments; product vouchers; co-pay vouchers; and prompt payment and other discounts.

Cornerstone establishes revenue reserves on a product-by-product basis as its best estimate at the time of sale based on historical experience for each product adjusted to reflect known changes in the factors that impact such reserves. Reserves for chargebacks, rebates, vouchers and related allowances are established based upon contractual terms with customers; analysis of historical levels of discounts, chargebacks, rebates and voucher redemptions; communications with customers; purchased information about the rate of prescriptions being written and the levels of inventory remaining in the distribution channel; expectations about the market for each product; and anticipated introduction of competitive products. The reserves for returns, rebates and price adjustments are the most significant estimates used in the recognition of revenue from product sales.

Consistent with industry practice, Cornerstone offers customers the ability to return products in the six months prior to, and the 12 months after, the products expire. Cornerstone adjusts its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include its estimate of inventory levels of its products in the distribution channel, the shelf life of the product shipped, competitive issues such as new product entrants and other known changes in sales trends. Cornerstone evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve accordingly.

Cornerstone's estimates of product rebates and price adjustments are based on its estimated mix of sales to various third-party payors, which are entitled either contractually or statutorily to discounts from Cornerstone's listed prices of its products. Cornerstone makes these judgments based upon the facts and circumstances known to it in accordance with GAAP. In the event that the sales mix to third-party payors is different from its estimates, Cornerstone may be required to pay higher or lower total rebates than it has estimated.

The following table provides a summary of activity with respect to Cornerstone's sales allowances:

	<b>Sales Returns</b>	<b>Rebates</b>	<b>Chargebacks</b>	<b>Price Adjustments</b>
	<b>(In thousands)</b>			
Balance at December 31, 2004	\$ 282	\$ 125		\$ (5)
Current provision	5,792	232	1,194	884
Payments and credits	(156)	(138)	(381)	(606)
Balance at December 31, 2005	5,918	219	813	273
Current provision	3,021	72	600	244
Payments and credits	(3,158)	(151)	(1,023)	(220)
Balance at December 31, 2006	5,781	140	390	297
Current provision	2,902	227	185	1,074
Payment and credits	(3,770)	(64)	(388)	(730)
Balance at December 31, 2007	4,913	303	187	641
Current provision	1,064	101		104
Payment and credits	(522)	(197)	(1)	(127)

Balance at March 31, 2008	\$	5,455	\$	207	\$	186	\$	618
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Sales returns are Cornerstone's most significant category of sales allowances. Sales returns were \$1.1 million in the first quarter of 2008, or 10% of gross product sales. Sales returns were \$2.9 million, \$3.0 million and \$5.8 million in 2007, 2006 and 2005, respectively, representing 9%, 12% and 25% of gross product sales in 2007, 2006 and 2005, respectively. The higher rate of sales returns in 2005 is primarily due to the January 2006 reduction in force, which resulted in Cornerstone having excess BALACET 325 inventory in the distribution channel as of December 31, 2005.

Rebates were \$101,000 in the first quarter of 2008, or 1% of gross product sales. Rebates were \$227,000, \$72,000 and \$232,000 in 2007, 2006 and 2005, respectively, representing approximately 1% or less of gross product sales in all three years.

There was no allowance for chargebacks in the first quarter of 2008. Chargebacks were \$185,000, \$600,000 and \$1.2 million in 2007, 2006 and 2005, respectively, representing approximately 1%, 2% and 5% of gross product sales in 2007, 2006 and 2005, respectively.

Price adjustments were \$104,000 in the first quarter of 2008, or 1% of gross product sales. Price adjustments were \$1.1 million, \$244,000 and \$884,000 in 2007, 2006 and 2005, respectively, representing approximately 3%, 1% and 4% of gross product sales in 2007, 2006 and 2005, respectively.

*Royalty Agreement Revenues.* Cornerstone also receives royalties under license agreements with a number of third parties that sell products to which Cornerstone has rights. The license agreements provide for the payment of royalties based on sales of the licensed product. These revenues are recorded based on estimates of the sales that occurred in the relevant period. The relevant period estimates of sales are based on interim data provided by the licensees and analysis of historical royalties paid, adjusted for any changes in facts and circumstances, as appropriate. Cornerstone maintains regular communication with its licensees to gauge the reasonableness of its estimates. Differences between actual royalty agreement revenues and estimated royalty agreement revenues are reconciled and adjusted for in the period in which they become known, typically the following quarter.

*Collaboration Agreement Revenues.* Cornerstone recognized collaboration agreement revenues as a result of a co-promotion agreement with Lupin Pharmaceuticals. Revenues associated with this agreement was recognized based on the calculation of shared revenues using an agreed-upon average sales price that was applied to the sales volume generated by Cornerstone. The sales volume was based on an analysis of prescription-level data by assigned, targeted prescribers within the United States.

### ***Product Rights***

Product rights are capitalized as incurred and are amortized over the estimated useful life of the product or the remaining trademark or patent life, whichever is shorter, on a straight-line or other basis to match the economic benefit received. Amortization begins once FDA approval has been obtained and commercialization of the product begins. Cornerstone evaluates its product rights annually to determine whether a revision to their useful lives should be made. This evaluation is based on Cornerstone's management's projection of the future cash flows associated with the products. At March 31, 2008, Cornerstone had an aggregate of \$13.6 million in capitalized products rights, which it expects to amortize over a period of one to 15 years.

### ***Inventory***

Inventory consists of raw materials, work in process and finished goods. Raw materials include the API for a product to be manufactured, work in process includes the bulk inventory of tablets that are in the process of being packaged for sale, and finished goods include pharmaceutical products ready for commercial sale or distribution as samples. Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out, or FIFO, method. Cornerstone's estimate of the net realizable value of its inventories is subject to judgment and estimation. The actual net realizable value of its inventories could vary significantly from its estimates and could have a material effect on its financial condition and results of operations in any reporting period. In evaluating whether inventory is stated at the lower of cost or market, Cornerstone considers such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. On a quarterly basis, Cornerstone analyzes its inventory levels and



writes down inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. At March 31, 2008, Cornerstone had an inventory reserve of \$168,000. The inventory reserve includes provisions for inventory that management believes will become short-dated before being sold. Short-dated inventory is

inventory that has not expired yet, but which wholesalers or pharmacies refuse to purchase because of its near-term expiration date. As of March 31, 2008, Cornerstone had \$3.9 million in inventory.

### ***Accrued Expenses***

As part of the process of preparing its consolidated financial statements, Cornerstone is required to estimate certain expenses. This process involves identifying services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in its consolidated financial statements. Examples of estimated expenses for which Cornerstone accrues include research and development expenses, reserves for product returns, rebates to third parties, including government programs such as Medicaid or private insurers, royalties owed to third-parties on sales of products, interest owed on debt instruments, and compensation and benefits for employees.

### ***Stock-Based Compensation***

Effective January 1, 2006, Cornerstone adopted the fair value recognition provisions of SFAS 123(R), using the prospective application method, which requires Cornerstone to recognize compensation cost for all awards and awards granted or modified after January 1, 2006. Awards outstanding at January 1, 2006 continue to be accounted for using the accounting principles originally applied to the award. The expense associated with stock-based compensation is recognized on a straight-line basis over the service period of each award.

Prior to the adoption of SFAS 123(R), Cornerstone recognized employee stock-based compensation expense using the intrinsic value method, which measures stock-based compensation expense as the amount at which the market price of the stock at the date of grant exceeds the exercise price. Because the exercise price for options awarded to employees is equal to the fair value at the grant date, Cornerstone did not recognize compensation expense for stock options granted to employees prior to 2006.

Cornerstone accounts for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS 123(R). Cornerstone uses the Black-Scholes-Merton option-pricing model to calculate the fair value of stock-based compensation under SFAS 123(R). There are a number of assumptions used to calculate the fair value of stock options or restricted stock issued to employees under this pricing model.

The two factors that most affect stock-based compensation are the estimate of the underlying fair value of the Company's common stock and the estimate of the stock price volatility. Accounting for equity instruments granted by Cornerstone under SFAS 123(R) and EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, requires Cornerstone to estimate the fair value of the equity instruments granted. If Cornerstone's estimates of the fair value of these equity instruments are too high or too low, stock-based compensation expense will be overstated or understated, respectively. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services can be readily estimated, Cornerstone uses the value of such goods or services to determine the fair value of the equity instruments. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services cannot be readily estimated, as is true in connection with most compensatory stock options and warrants granted to employees and non-employees, Cornerstone estimates the fair value of the equity instruments based upon the consideration of factors that it deems to be relevant at the time using cost, market or income approaches to such valuations.

### **Results of Operations**

***Comparison of the Three Months Ended March 31, 2008 and 2007***

*Net Revenues*

*Net Product Sales.* Net product sales were \$9.0 million in the three months ended March 31, 2008, compared to \$8.2 million in the three months ended March 31, 2007, an increase of approximately \$785,000, or 10%.

Net product sales in the first quarter of 2008 and in the first quarter of 2007 consisted of revenues from sales of Cornerstone's ALLERX family of products and its SPECTRACEF, DECONSAL and BALACET 325 products. The increase in the first quarter of 2008 is primarily due to an increase of approximately \$1.4 million in net product sales of BALACET 325 as a result of purchases by wholesalers that occurred in January 2008 following a price increase. Cornerstone gave wholesalers the opportunity to purchase product at a discount off the new price. This increase was offset, in part, by a \$134,000 decrease in net product sales of the ALLERX Dose Pack family of products and a \$581,000 decrease in net product sales of SPECTRACEF. The decrease in net product sales of the ALLERX Dose Pack family of products was due to decreased net product sales of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack as a result of generic competition, which was mitigated, in part, by price increases on these products. Partially offsetting the decreases in net product sales of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack were increases in net product sales of the other ALLERX Dose Pack products as a result of a combination of price and volume increases. The decrease in net product sales of SPECTRACEF was due to lower wholesaler purchasing activity in the first quarter of 2008 due to sufficient supply of product in the distribution channel.

*Royalty Agreement Revenues.* Royalty agreement revenues were \$444,000 in the three months ended March 31, 2008, compared to \$471,000 in the three months ended March 31, 2007, a decrease of approximately \$27,000, or 6%. This decrease was primarily due to a \$58,000 decrease in royalty agreement revenues from Auriga based on EXTENDRYL sales, which resulted from decreased promotional activity by Auriga, offset, in part, by a \$35,000 increase in royalty agreement revenues from Pliva based on APAP 500 sales.

#### *Costs and Expenses*

*Cost of Product Sales.* Cost of product sales was \$565,000 in the three months ended March 31, 2008, compared to \$668,000 in the three months ended March 31, 2007, a decrease of approximately \$103,000, or 15%. Gross margin was approximately 94% in the three months ended March 31, 2008 and 92% in the three months ended March 31, 2007. Cost of product sales in both the first quarter of 2008 and the first quarter of 2007 consisted primarily of the expenses associated with manufacturing and distributing the ALLERX family of products, BALACET and SPECTRACEF, reserves established for excess or obsolete inventory and other direct costs of product sales, such as package inserts and artwork. Cornerstone established additional inventory obsolescence reserves of \$9,000 in the three months ended March 31, 2008 and \$45,000 in the three months ended March 31, 2007. The write-offs in both the first quarter of 2008 and the first quarter of 2007 resulted from excess or obsolete inventory that would have become short-dated prior to being sold.

*Sales and Marketing Expenses.* Sales and marketing expenses were \$3.9 million in the three months ended March 31, 2008, compared to \$2.1 million in the three months ended March 31, 2007, an increase of approximately \$1.8 million, or 90%. This increase was primarily due to the following:

- a \$354,000 increase in co-promotion expenses related to Cornerstone's BALACET 325, SPECTRACEF and ALLERX Dose Pack products;

- an \$827,000 increase in labor, benefits and related employee expenses and related expenses as a result of the expansion of Cornerstone's sales team in September 2007;

- a \$486,000 increase in advertising and promotion expenses for the DECONSAL products, the ALLERX Dose Pack family of products and SPECTRACEF, including a \$325,000 increase for product samples;

- a \$107,000 increase in consulting expenses primarily related to market research and consulting fees; and

- a \$98,000 increase in travel-related expenses that was due to the sales team expansion.

*Royalty Expenses.* Royalty expenses were \$1.2 million in the three months ended March 31, 2008, compared to \$1.2 million in the three months ended March 31, 2007, an increase of approximately \$65,000, or 6%. This increase was primarily due to increased sales of BALACET 325, offset, in part, by decreased sales of the ALLERX Dose Pack family of products, SPECTRACEF and APAP 500.

*General and Administrative Expenses.* General and administrative expenses were \$1.5 million in the three months ended March 31, 2008, compared to \$982,000 in the three months ended March 31, 2007, an increase of approximately \$522,000, or 53%. This increase was primarily due to a \$156,000 increase in labor, benefits, related employee expenses as a result of additional headcount; a \$26,000 increase stock-based compensation expense; \$159,000 in expenses related to Aristos, which began operations in November 2007; and a \$141,000 increase in legal and consulting fees related to the proposed merger with Critical Therapeutics.

*Research and Development Expenses.* Research and development expenses were \$98,000 in the three months ended March 31, 2008, compared to \$5,000 in the three months ended March 31, 2007. This increase was primarily due to:

a \$50,000 increase in expenses in connection with Cornerstone's SPECTRACEF life cycle extension programs, including expenses incurred related to development work related to the formulation of SPECTRACEF 400 mg and SPECTRACEF Once Daily; and

a \$43,000 increase in expenses related to the clinical studies for CBP 058 and the qualification of new manufacturing facilities to manufacture bulk tablets for the ALLERX product line.

*Amortization and Depreciation Expenses.* Amortization and depreciation expenses were \$758,000 in the three months ended March 31, 2008, compared to \$842,000 in the three months ended March 31, 2007, a decrease of approximately \$84,000, or 10%. This decrease was primarily due to the extension of the estimated useful life of the SPECTRACEF product rights as a result of the July 27, 2007 letter agreement with Meiji, offset, in part, by the capitalization of additional product rights. Cornerstone's product rights are related to BALACET AND SPECTRACEF.

*Other Charges.* Cornerstone did not incur any other charges for the quarter ended March 31, 2008. Other charges for the quarter ended March 31, 2007 consisted of \$109,000 in legal expenses related to the settlement of litigation.

#### *Other Expenses*

Interest expense, net, was \$378,000 in the three months ended March 31, 2008, compared to \$339,000 in the three months ended March 31, 2007, an increase of approximately \$39,000, or 12%. This increase was primarily due to the increase in the license agreement liability related to SPECTRACEF product rights, offset, in part, by a \$16,000 decrease in the interest expense related to the Paragon line of credit.

#### *Provision for Income Taxes*

The provision for income taxes from continuing operations was \$319,000 in the three months ended March 31, 2008, compared to \$632,000 in the three months ended March 31, 2007. This decrease in the provision for income taxes was due to the decrease in income before income taxes from \$2.5 million in the three months ended March 31, 2007 to \$988,000 in the three months ended March 31, 2008. The effective tax rate was 32.3% for the three months ended March 31, 2008 and 25.2% for the three months ended March 31, 2007.

#### *Comparison of the Year Ended December 31, 2007 and 2006*

##### *Net Revenues*

*Net Product Sales.* Net product sales were \$26.2 million in 2007, compared to \$20.4 million in 2006, an increase of approximately \$5.8 million, or 28%. Net product sales in 2007 and 2006 consisted of revenues from sales of Cornerstone's ALLERX family of products and its SPECTRACEF, DECONSAL and BALACET 325 products. The increase in 2007 is primarily due to:

a \$6.6 million increase in net product sales of SPECTRACEF, which was launched in November 2006; and

a \$1.5 million increase in net product sales of BALACET 325 that was primarily due to a 63% increase in the product's wholesale acquisition price.

These increases in net product sales were offset, in part, by:

a \$1.3 million decrease in net product sales of DECONSAL products as a result of the FDA's requirement that DECONSAL II be removed from the market and the decline in sales of the DECONSAL CT Tannate Chewable Tablets and DECONSAL DM Tannate Chewable Tablets because initial sales in 2006 of the chewable tablets to wholesalers for inventory in the distribution channel were not repeated in 2007; and

a \$791,000 decrease in net product sales of the ALLERX Dose Pack family of products as a result of increased generic competition.

*Royalty Agreement Revenues.* Royalty agreement revenues were \$1.8 million in 2007, compared to \$1.7 million in 2006, an increase of approximately \$146,000, or 9%. This increase was primarily due to a \$640,000 increase in royalty agreement revenues from APAP 500 and a \$332,000 increase in royalty agreement revenues received pursuant to a settlement agreement with a competitor that had infringed the '796 Patent by selling generic equivalents of the former formulation of ALLERX 10 Dose Pack and ALLERX 30 Dose Pack. These increases were offset, in part, by a \$826,000 decrease in royalty agreement revenues relating to EXTENDRYL as a result of an increase in product returns experienced by the licensee, Auriga, in 2007.

#### *Costs and Expenses*

*Cost of Product Sales.* Cost of product sales was \$3.3 million in 2007, compared to \$2.2 million in 2006, an increase of approximately \$1.1 million, or 53%. Gross margin was 87% in 2007 and 89% in 2006. Cost of product sales in 2007 and 2006 consisted primarily of the expenses associated with manufacturing and distributing products, including the ALLERX Dose Pack family of products and the SPECTRACEF, BALACET 325 and DECONSAL products, and reserves established for excess or obsolete inventory. Cornerstone recorded inventory write-offs of \$169,000 in 2007. The write-offs in 2007 resulted from excess or obsolete inventory that, due to its expiration dating, would not be sold. In 2006, Cornerstone reduced its inventory reserve by \$101,000 as a result of repackaging as samples commercial product that had been reserved for in 2005 because management believed that it had become unsalable because it was short-dated.

*Sales and Marketing Expenses.* Sales and marketing expenses were \$10.4 million in 2007, compared to \$7.1 million in 2006, an increase of approximately \$3.3 million, or 46%. This increase was primarily due to the following:

a \$1.3 million increase in advertising and promotional expenses primarily due to samples and sample distribution;

a \$1.8 million increase in labor, benefits and related employee expenses as a result of the expansion of Cornerstone's sales team in 2007;

a \$670,000 increase in the co-promotion fee paid for the promotion of the ALLERX Dose Pack family of products, BALACET 325 and SPECTRACEF;

a \$576,000 increase in stock-based compensation expense; and

a \$618,000 increase in travel and other employee related expenses due to the hiring of 78 additional sales representatives in 2007.



These increases were offset, in part, by a \$1.5 million reimbursement of sales and marketing expenses by Meiji to support Cornerstone's sales force expansion in the third quarter of 2007.

*Royalty Expenses.* Royalty expenses were \$3.4 million in 2007, compared to \$1.7 million in 2006, an increase of approximately \$1.7 million, or 105%. This increase was primarily due to higher sales of BALACET 325 and SPECTRACEF, offset, in part, by lower sales of DECONSAL products. In addition, royalty expenses related to the ALLERX Dose Pack family of products increased in 2007 due to new royalty obligations under settlement agreements entered into by Cornerstone in 2007 with generic competitors in exchange for such competitors' agreement to withdraw their challenges to the validity of the '796 Patent and to

cease marketing products that compete with the ALLERX Dose Pack family of products. These additional royalty agreements increased royalty expenses \$475,000 as compared to 2006.

*General and Administrative Expenses.* General and administrative expenses were \$4.1 million in 2007, compared to \$3.7 million in 2006, an increase of approximately \$428,000, or 12%. This increase was primarily due to a \$519,000 increase in labor, benefits, related employee expenses and stock-based compensation expense principally related to Cornerstone's executive, finance and regulatory functions. This increase was offset, in part, by an \$83,000 decrease in audit, legal and consulting expenses.

*Research and Development Expenses.* Research and development expenses were \$948,000 in 2007, compared to \$249,000 in 2006, an increase of approximately \$699,000, or 280%. This increase was primarily due to:

- a \$474,000 increase in expenses in connection with Cornerstone's SPECTRACEF life cycle extension programs, including expenses incurred for a bioequivalence study, the sNDA submission for SPECTRACEF 400 mg and related consulting costs; and

- a \$171,000 increase in expenses primarily related to validation studies and manufacturing methodology and technology transfer in connection with a change in Cornerstone's third-party manufacturing site used to produce bulk tablets for the ALLERX product line.

*Amortization and Depreciation Expenses.* Amortization and depreciation expenses were \$3.2 million in 2007, compared to \$2.7 million in 2006, an increase of approximately \$527,000, or 19%. This increase was primarily due to Cornerstone's acquisition of the SPECTRACEF product rights in October 2006, which Cornerstone began amortizing in November 2006.

*Other Charges.* Other charges were \$245,000 in 2007, compared to \$3.6 million in 2006, a decrease of approximately \$3.3 million, or 93%. In 2007, other charges consisted of expenses related to the settlement of litigation. In 2006, other charges consisted of \$1.2 million of expenses related to litigation with Lupin Pharmaceuticals and Lupin Ltd., \$1.7 million of expenses related to the forfeiture of the Lupin Ltd. product rights, \$472,000 of expenses related to litigation with generic competitors and \$240,000 of foregone merger costs.

#### *Other Expenses*

*Interest Expense, net.* Net interest expense was \$1.4 million in 2007, compared to \$1.3 million in 2006, an increase of approximately \$170,000, or 14%. This increase was primarily due to a \$283,000 increase in interest expense related to the SPECTRACEF license agreement liability, offset, in part, by a \$135,000 decrease in interest expense related to the Carolina Note and a \$21,000 decrease in interest expense related to the Paragon line of credit. In addition, interest earned on related party notes decreased by \$43,000.

*Loss on Marketable Security.* Also included in other expense in 2007 was \$324,000 related to losses on marketable securities related to the Cornerstone investment in Auriga. Cornerstone recorded this loss as the result of management's determination that the decline in the value of these securities was other than temporary. There were no losses on marketable securities in 2006.

#### *Provision for Income Taxes*

The provision for income taxes was \$130,000 in 2007, compared to \$0 in 2006. This increase is due to income before income taxes of \$701,000 in 2007, compared to a loss before income taxes of \$305,000 in 2006. The effective tax rate was 18.6% in 2007 and 0% in 2006.

***Comparison of the Year Ended December 31, 2006 and 2005***

*Net Revenues*

*Net Product Sales.* Net product sales were \$20.4 million in 2006, compared to \$15.6 million in 2005, an increase of approximately \$4.8 million, or 31%. Net product sales in 2006 and 2005 related to sales of its marketed products, including its ALLERX Dose Pack family of products and DECONSAL and BALACET

325 products. Net product sales in 2006 also included initial sales of SPECTRACEF. The increase in net product sales is primarily due to:

a \$3.1 million increase in net product sales of ALLERX Dose Pack family of products as a result of commercial launches of ALLERX Dose Pack DF in August 2006 and ALLERX Dose Pack PE in September 2006. In addition, Cornerstone increased the prices of the ALLERX Dose Pack family of products, ALLERX D and ALLERX Suspension an average of 16%, 26% and 14%, respectively, in 2006 as compared to 2005, which offset decreases in unit volume of these products and resulted in an increase in net product sales of \$750,000.

a \$1.3 million increase in net product sales of BALACET 325 due to increased product demand and a full year of sales in 2006, as Cornerstone launched this product in April 2005;

\$1.1 million in net product sales of its DECONSAL chewables as a result of their commercial launch in October 2006; and

a \$272,000 increase in net product sales of SPECTRACEF as a result of its commercial launch in November 2006.

These increases were offset, in part, by a \$909,000 decrease in net product sales of DECONSAL II due to there being sufficient quantities of product at wholesalers during 2006 due to purchases by wholesalers that occurred in November 2005 as a result of a price increase. Cornerstone gave wholesalers a one-time opportunity to purchase product at the price in effect prior to the increase. In addition, there was a \$584,000 decrease in net product sales of EXTENDRYL, which Cornerstone licensed to Auriga in May 2005, and a \$384,000 decrease in net product sales of Humibid, which Cornerstone licensed to Adams in February 2005.

*Royalty Agreement Revenues.* Royalty agreement revenues were \$1.7 million in 2006, compared to \$753,000 in 2005, an increase of approximately \$925,000, or 123%. Over one-half of this increase was due to the royalty agreement revenues related to APAP 500, which Cornerstone acquired from Vintage in July 2004 and licensed to Pliva in September 2005. In addition, EXTENDRYL royalty agreement revenues increased significantly as a result of increased sales by Auriga.

*Collaboration Agreement Revenues.* Collaboration agreement revenues were \$0 in 2006, compared to \$1.1 million in 2005. This decrease results from the February 2006 termination of the co-promotion agreement with Lupin for Suprax.

#### *Costs and Expenses*

*Cost of Product Sales.* Cost of product sales was \$2.2 million in 2006, compared to \$3.4 million in 2005, a decrease of approximately \$1.2 million, or 37%. Gross margin was 89% in 2006 and 80% in 2005. The profit margin improvement resulted from effective negotiations with manufacturers regarding product costs and utilization of bulk product manufacturing and alternate packaging resources. Cornerstone's cost of product sales in 2006 consisted primarily of expenses associated with manufacturing and distributing its ALLERX Dose Pack family of products and its SPECTRACEF, DECONSAL II and BALACET 325 products, and reserves established for excess or obsolete inventory. Cost of product sales in 2005 consisted primarily of expenses associated with manufacturing and distributing its ALLERX Dose Pack family of products and its DECONSAL, BALACET 325 and EXTENDRYL products, and reserves established for excess or obsolete inventory. In 2006, Cornerstone adjusted its inventory reserve by \$101,000 as a result of packaging as samples inventory of its BALACET 325 commercial product that had been reserved in 2005 because it was previously thought to be unsalable. Cornerstone recorded inventory write-offs of \$328,000 in 2005 for excess or obsolete inventory that due to its expiration dating was not expected to be sold.

*Sales and Marketing Expenses.* Sales and marketing expenses were \$7.1 million in 2006, compared to \$13.9 million in 2005, a decrease of approximately \$6.8 million, or 49%. The decrease in sales and marketing expenses in 2006 was primarily due to the January 2006 reduction in force, which is categorized as follows:

a \$1.8 million decrease in labor, benefits and related employee expenses for sales and marketing personnel;

- a \$3.8 million decrease in advertising and promotional expenses;
- a \$684,000 decrease in travel and related expenses as a result of the smaller sales team in 2006;
- a \$300,000 decrease in consulting expenses due to less marketing research being conducted in 2006; and
- a \$180,000 decrease in office supplies and related expenses as a result of the smaller sales team in 2006.

*Royalty Expenses.* Royalty expenses were \$1.7 million in 2006, compared to \$1.9 million in 2005, a decrease of approximately \$270,000, or 14%. This decrease was primarily due to lower sales of Cornerstone's BALACET 325, DECONSAL and EXTENDRYL products, offset, in part, by higher sales of Cornerstone's ALLERX Dose Pack family of products and APAP 500.

*General and Administrative Expenses.* General and administrative expenses were \$3.7 million in 2006, compared to \$4.9 million in 2005, a decrease of approximately \$1.2 million, or 25%. This decrease was primarily due to a \$594,000 decrease in legal and consulting expenses, \$390,000 of bad debt expense recorded in 2005 related to accounts receivable due from Lupin under the co-promotion agreement that the parties terminated in 2006, a \$298,000 decrease in expenses related to Cornerstone's defined benefit plan as a result of Cornerstone's termination of the plan in March 2006 and a \$104,000 decrease in labor, benefits and related employee expenses. This decrease was offset, in part, by a \$94,000 increase in Cornerstone's incentive bonus and other compensation expenses and a \$110,000 increase in travel expenses.

*Research and Development Expenses.* Research and development expenses were \$249,000 in 2006, compared to \$266,000 in 2005, a decrease of approximately \$17,000, or 6%. This decrease was primarily due to a \$258,000 decrease in expenses as a result of Cornerstone ceasing development of a product candidate with the API cephalixin, offset, in part, by a \$231,000 increase primarily related to product development of the ALLERX family of products.

*Amortization and Depreciation Expenses.* Amortization and depreciation expenses were \$2.7 million in 2006, compared to \$1.9 million in 2005, an increase of approximately \$765,000, or 39%. The increase in 2006 was primarily due to a full year of amortization of the BALACET rights, which Cornerstone acquired in July 2004 and began amortizing in April 2005, and the acquisition of the SPECTRACEF rights, which Cornerstone acquired in October 2006 and began amortizing in November 2006.

*Other Charges.* Other charges were \$3.6 million in 2006, compared to \$1.0 million in 2005, an increase of approximately \$2.6 million, or 258%. In 2006, other charges consisted of legal and settlement expenses of \$1.7 million related to litigation with Lupin Pharmaceuticals, Lupin Ltd. and generic competitors, foregone merger costs of \$240,000 and the forfeiture the Lupin Ltd. product rights of \$1.7 million. In 2005, other charges consisted of the forfeiture of a standstill payment to Advancis. The payment allowed Cornerstone to preserve and extend its rights to purchase a trademark that was to be used upon the launch of an extended-release cephalixin product. When this project was abandoned by Cornerstone's management at the end of 2005, the trademark was no longer necessary, and Cornerstone therefore forfeited the standstill payment.

#### *Other Expenses*

*Interest Expense, net.* Net interest expense was \$1.2 million in 2006, compared to \$1.6 million in 2005, a decrease of approximately \$317,000, or 20%. This decrease was primarily due to a \$224,000 decrease in interest expense related to the Carolina Note and a decrease of \$220,000 in interest expense related to the Paragon line of credit, offset, in part, by a \$34,000 increase in interest expense related to the SPECTRACEF license agreement and a \$95,000 decrease in

the interest earned on the note receivable from Cornerstone Biopharma Holdings, Ltd. The decrease in interest expense was due to a \$3.6 million reduction in the principal amount outstanding under the Carolina Note as a result of a June 2006 agreement whereby Cornerstone and Carolina Pharmaceuticals agreed to a net offset of \$5.4 million in combined principal and accrued interest outstanding under the Carolina Note against equal amounts due to Cornerstone from

Cornerstone Biopharma Holdings, Ltd. and Carolina Pharmaceuticals. The amounts due to Cornerstone primarily resulted from the 2005 Adams litigation settlement.

## Liquidity and Capital Resources

### Sources of Liquidity

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 approximately \$669,000 in the quarter ended March 31, 2008 and \$571,000 in the year ended December 31, 2007. Cornerstone requires cash to meet its operating expenses and for capital expenditures, acquisitions and in-licenses of rights to products and principal and interest payments on its debt. To date, Cornerstone has funded its operations primarily from product sales, royalty agreement revenues and borrowings under the Carolina Note and the Paragon line of credit. As of March 31, 2008, Cornerstone had \$416,000 in cash and cash equivalents.

### Cash Flows

The following table provides information regarding Cornerstone's cash flows for the years ended December 31, 2007, 2006 and 2005 and the three months ended March 31, 2008 and 2007.

	Year Ended December 31,			Three Months Ended March 31,	
	2007	2006	2005	2008	2007
		(Audited)		(Unaudited)	
	(In thousands)				
Cash provided by (used in):					
Operating activities	\$ 1,563	\$ 950	\$ 610	\$ 2,193	172
Investing activities	(718)	(714)	(2,648)	(1,018)	\$ (280)
Financing activities	(720)	(1,079)	(1,011)	(1,000)	550
Net increase/(decrease) in cash and cash equivalents	\$ 125	\$ (843)	\$ (3,049)	\$ 175	\$ 442

### Net Cash Provided By Operating Activities

Net cash provided by operating activities in the three months ended March 31, 2008 primarily reflected Cornerstone's net income of \$669,000, adjusted by non-cash expenses totaling \$842,000 and changes in accounts receivable, inventories, accrued expenses and other operating assets and liabilities. Non-cash items included amortization and depreciation of \$758,000 and stock-based compensation expense of \$84,000. Accounts receivable decreased \$624,000 from December 31, 2007, primarily due to product sales at the end of 2007. Inventories increased \$857,000 from December 31, 2007, primarily due to increases in the amount of SPECTRACEF trade product on hand at March 31, 2008 as compared to December 31, 2007. Accrued expenses increased \$809,000 from December 31, 2007, primarily due to increases in accrued sales allowances and interest payable.

Net cash provided by operating activities in the three months ended March 31, 2007 primarily reflected Cornerstone's net income of \$1.9 million, adjusted by non-cash expenses totaling \$891,000 and changes in accounts receivable, accrued expenses, income taxes payable and other operating assets and liabilities. Non-cash items included



amortization and depreciation of \$842,000 and stock-based compensation expense of \$49,000. Accounts receivable increased \$3.6 million from December 31, 2006, primarily due to increased sales of ALLERX Dose Pack products in February and March 2007. Accrued expenses increased \$657,000 from December 31, 2006, primarily due to increases in sales allowances and interest accruals, offset, in part, by decreases in the accrual for litigation settlements due to payments that occurred during the first quarter of 2007. Income taxes payable increased \$632,000 from December 31, 2006, primarily due to income recognized during the first three months of 2007.

Net cash provided by operating activities in 2007 reflected Cornerstone's net income of \$570,000, adjusted by non-cash expenses totaling \$4.4 million and changes in accounts receivable, inventories, accrued expenses and

other operating assets and liabilities. Non-cash items included amortization and depreciation of \$3.2 million, issuance of a warrant for services of \$507,800, stock-based compensation expense of \$293,000 and loss on Cornerstone's investment in Auriga common stock of \$324,000. Accounts receivable increased \$4.2 million from December 31, 2006, primarily due to increased sales at the end of 2007. Inventories increased \$1.2 million from December 31, 2006, primarily due to stocking and lead time requirements related to the manufacturing of SPECTRACEF. Accrued expenses increased \$1.0 million from December 31, 2006, primarily due to increased accruals for royalty expenses of \$1.5 million and interest expense of \$941,000, offset, in part, by a decrease in sales allowances of \$475,000 and accrued settlement expenses of \$1.1 million.

Net cash provided by operating activities in 2006 reflected Cornerstone's net loss of \$305,000, adjusted by non-cash items totaling \$4.1 million and changes in inventories, accounts payable, accrued expenses and other operating assets and liabilities. Non-cash items primarily included amortization and depreciation of \$2.7 million, forfeiture of product rights of \$1.7 million related to Cornerstone's settlement agreement with Lupin Pharmaceuticals and Lupin Ltd. and receipt of shares of Auriga common stock for royalties of \$332,000.

Inventories increased \$600,000 from December 31, 2005, primarily due to stocking and lead time requirements related to the manufacturing of SPECTRACEF. In addition, Cornerstone shipped \$1.0 million of inventory on behalf of Carolina Pharmaceuticals in relation to a settlement with AmerisourceBergen. Accounts payable decreased \$1.1 million from December 31, 2005, primarily due to timing of payments to vendors. There was a \$1.3 million decrease in accrued expenses resulting from a \$1.8 million decrease in accrued interest outstanding under the Carolina Note, a \$705,000 decrease in sales allowances, a \$1.1 million decrease in accrued royalties and a \$751,000 decrease in accrued interest, offset, in part, by a \$1.1 million increase in arbitration settlement accruals. The \$1.8 million decrease in accrued interest under the Carolina Note resulted from the June 2006 agreement between Cornerstone and Carolina Pharmaceuticals to offset \$3.6 million in principal and \$1.8 million in accrued interest outstanding under the Carolina Note against equal amounts due to Cornerstone from a related party.

Net cash provided by operating activities in 2005 reflected Cornerstone's net loss of \$11.4 million, adjusted by non-cash expenses totaling \$2.2 million and changes in accounts receivable, inventories, accrued expenses and other operating assets and liabilities. Non-cash items primarily included amortization and depreciation of \$1.9 million and amortization of debt discount related to a loan with Vintage. Accounts receivable decreased \$1.8 million from December 31, 2004, primarily due to lower levels of year-end shipments as compared to the previous year. Inventories decreased \$690,000 from December 31, 2004, primarily due to lower levels of Humibid inventory after rights to this product were transferred to Adams in February 2005 as a result of the January 2005 settlement of litigation. Accrued expenses increased \$7.6 million from December 31, 2004, primarily due to increases in sales allowances.

#### ***Net Cash Used in Investing Activities***

Net cash used in investing activities in the three months ended March 31, 2008 primarily reflected the purchase of product rights for \$1.0 million.

Net cash used in investing activities in the three months ended March 31, 2007 primarily reflected net advances to related parties of \$205,000 and the purchase of product rights for \$75,000.

Net cash used in investing activities in 2007 primarily reflected net advances to related parties of \$613,000, purchases of product rights for \$75,000 and purchases of property and equipment of \$64,000, offset, in part, by net proceeds received from the net collection of deposits of \$35,000.

Net cash used in investing activities in 2006 primarily reflected the purchase of Neos products rights for \$500,000, net advances to related parties of \$140,000, the payment for deposits of \$55,000 and purchases of property and equipment

of \$57,000.

Net cash used in investing activities in 2005 primarily reflected payment for Lupin product rights of \$1.5 million, net advances to related parties of \$1.1 million and purchases of property and equipment of \$124,000. These amounts were offset, in part, by proceeds from the release of restricted cash of \$68,000.

*Net Cash Used in Financing Activities*

Net cash used in financing activities in the three months ended March 31, 2008 reflected net payments on the Paragon line of credit of \$1.0 million.

Net cash provided by financing activities in the three months ended March 31, 2007 reflected net proceeds from the Paragon line of credit of \$550,000.

Net cash used in financing activities in 2007 reflected principal payments on the SPECTRACEF license agreement liability of \$720,000.

Net cash used in financing activities in 2006 primarily reflected principal payments on the SPECTRACEF license agreement liability of \$250,000, net proceeds from the Paragon line of credit of \$1.3 million, a principal payment on a note payable to Vintage of \$1.5 million and \$547,000 related to the repurchase of a warrant in connection with Cornerstone's settlement agreement with Lupin.

Net cash used in financing activities in 2005 primarily reflected a principal payment on a note payable to Vintage of \$1.5 million, offset, in part, by net proceeds from the Paragon line of credit of \$500,000.

*Funding Requirements*

Cornerstone expects to continue to incur significant development and commercialization expenses as it seeks FDA approval for 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 team 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. Accordingly, Cornerstone will need to increase its revenues to be able to sustain and increase its profitability on an annual and quarterly basis. There is no assurance that Cornerstone will be able to do so. Cornerstone's failure to achieve consistent profitability could impair its ability to raise capital, expand its business, diversify its product offerings and continue its operations.

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

- the level of product sales of 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

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.

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. Cornerstone's only committed external source of funds is borrowing availability under the Paragon line of credit, which is personally guaranteed by Cornerstone's President and Chief Executive Officer and Carolina Pharmaceuticals, Inc., a company under common control with Cornerstone, as described in more detail below under *Debt Financing Paragon Line of Credit*. Cornerstone's ability to borrow under the Paragon line of credit is subject to its satisfaction of specified conditions. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

As of March 31, 2008, Cornerstone had approximately \$416,000 of cash and cash equivalents on hand and borrowing availability of \$3.25 million under the Paragon line of credit. Based on its current operating plans, Cornerstone believes that its existing cash and cash equivalents, revenues from product sales and borrowing availability under the Paragon 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.

#### *Debt Financing*

*Carolina Note.* In April 2004, Cornerstone entered into the Carolina Note with Carolina Pharmaceuticals to borrow up to \$15.0 million for five years with an annual interest rate of 10%. Cornerstone borrowed \$13.0 million under the Carolina Note in April 2004. In June 2006, Cornerstone and Carolina Pharmaceuticals agreed to offset \$3.6 million in principal and \$1.8 million in accrued interest outstanding under the Carolina Note against equal amounts due to Cornerstone from a related party. As of March 31, 2008, there was \$9.4 million in principal and \$1.7 million in accrued interest outstanding under Carolina Note. In connection with the merger agreement, Carolina Pharmaceuticals, Cornerstone and Critical Therapeutics entered into a noteholder agreement that provides, among other things, for the conversion or exchange of the outstanding principal amount of the Carolina Note into shares of Cornerstone's common stock prior to the effective time of the merger.

*Paragon Line of Credit.* In April 2005, Cornerstone obtained financing under a bank line of credit for up to \$4.0 million with Paragon Commercial Bank. Cornerstone has used the Paragon line of credit to fund its general operations and product acquisitions. As amended and renewed in June 2008, the Paragon line of credit is subject to a monthly borrowing base equal to 75% of Cornerstone's accounts receivable balances outstanding 90 days or less and 100% of the \$500,000 assignment of deposits to Cornerstone by Cornerstone's President and Chief Executive Officer. As of March 31, 2008, Cornerstone had \$750,000 outstanding under the Paragon line of credit and \$3.25 million in available borrowing capacity. Cornerstone is currently considering financing alternatives to fund capital expenditures in the future.

Amounts outstanding under the Paragon line of credit bear interest at a variable rate equal to the Wall Street Journal prime rate, which was 5.25% as of March 31, 2008. The Paragon line of credit is collateralized by Cornerstone's accounts receivable, inventories, intangible assets, other personal property, a \$2.0 million deed of trust on the personal residence of Cornerstone's President and Chief Executive Officer and an assignment of deposits in the amount of \$500,000 to Cornerstone by Cornerstone's President and Chief Executive Officer. Cornerstone's President and Chief Executive Officer and Carolina Pharmaceuticals, Inc., a company under common control with Cornerstone, have jointly guaranteed the Paragon line of credit. The Paragon line of credit requires, among other requirements, that the Carolina Note be subordinated to the Paragon line of credit, that Cornerstone not incur any additional debt without Paragon's consent and that Cornerstone's President and Chief Executive Officer maintains a certain level of liquid assets and a majority ownership in Cornerstone. Interest is due monthly with all outstanding principal due on maturity in June 2009.

**Contractual Obligations**

The following table summarizes Cornerstone's known fixed contractual obligations as of December 31, 2007.

Contractual Obligations	Total	Payments Due by Period			More Than 5 Years
		Less Than 1 Year	1-3 Years	3-5 Years	
		(In thousands)			
Long-term debt obligations(1)	\$ 12,653	1,750	10,903		
Capital lease obligations					
Operating lease obligations(2)	333	262	71		
Purchase obligations(3)	6,704	3,302	2,202	1,200	
Other long-term liabilities reflected on Cornerstone's balance sheet under GAAP(4)	4,750	1,000	2,250	1,500	
Total contractual obligations	\$ 24,440	6,314	15,426	2,700	

- (1) Long-term debt obligations include principal and interest due under the Paragon line of credit and the Carolina Note. See Notes 4 and 5 to Cornerstone's consolidated financial statements beginning on page F-69 of this proxy statement/prospectus for a description of the amounts due under the Paragon line of credit and the Carolina Note, respectively.
- (2) Operating leases include minimum payments under leases for Cornerstone's facilities, automobiles and certain equipment.
- (3) Purchase obligations include fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers; clinical trial and research agreements with contract research organizations and consultants; and agreements with providers of marketing analytical services. Cornerstone's license and supply agreement with Meiji requires Cornerstone to purchase a minimum quantity of cefditoren pivoxil, the API of SPECTRACEF, each contract year through March 2012 at a price that is subject to customary annual increases. In determining the purchase obligations due to Meiji for purposes of the contractual obligations table, Cornerstone used the price for cefditoren pivoxil in effect on December 31, 2007. Purchase obligations do not include any contingent contractual payments that Cornerstone may be required to make that depend on the achievement of scientific, regulatory or commercial milestones, or any contingent contractual royalty payments.
- (4) Other long-term liabilities include principal and interest due under Cornerstone's license agreement liability with Meiji. See Note 3 to Cornerstone's consolidated financial statements beginning on page F-69 of this proxy statement/prospectus for a description of the amounts due under the license agreement liability.

In connection with a noteholder agreement entered into by Cornerstone, Carolina Pharmaceuticals and Critical Therapeutics in connection with Cornerstone's merger with Critical Therapeutics, Cornerstone is required to repay the Carolina Note prior to the closing of the merger by converting the principal amount outstanding under the Carolina Note into shares of Cornerstone common stock. Cornerstone anticipates that all accrued interest under the Carolina Note will be paid in cash at or prior to the time the principal amount outstanding under the Carolina Note is converted.

**Off-Balance Sheet Arrangements**

Since inception, Cornerstone has not engaged in any off-balance sheet arrangements, including structured finance, special purpose entities or variable interest entities.

**Effects of Inflation**

Cornerstone does not believe that inflation has had a significant impact on its revenues or results of operations since inception. Cornerstone expects its cost of product sales and other operating expenses will change in the



future in line with periodic inflationary changes in price levels. Because Cornerstone intends to retain and continue to use its property and equipment, Cornerstone believes that the incremental inflation related to the replacement costs of such items will not materially affect its operations. However, the rate of inflation affects Cornerstone's expenses, such as those for employee compensation and contract services, which could increase its level of expenses and the rate at which it uses its resources. While Cornerstone's management generally believes that Cornerstone will be able to offset the effect of price-level changes by adjusting its product prices and implementing operating efficiencies, any material unfavorable changes in price levels could have a material adverse affect on Cornerstone's financial condition, results of operations and cash flows.

### **Recent Accounting Pronouncements**

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP, or the GAAP hierarchy. SFAS 162 makes the GAAP hierarchy explicitly and directly applicable to preparers of financial statements, a step that recognizes preparers' responsibilities for selecting the accounting principles for their financial statements, and sets the stage for making the framework of FASB Concept Statements fully authoritative. The effective date for SFAS 162 is 60 days following the SEC's approval of the Public Company Accounting Oversight Board's related amendments to remove the GAAP hierarchy from auditing standards, where it has resided for some time. Cornerstone does not expect the adoption of SFAS 162 to have a material impact on its financial statements.

In April 2008, the FASB issued FASB Staff Position Financial Accounting Standard 142-3, *Determination of the Useful Life of Intangible Assets*, or FSP FAS 142-3. FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, *Goodwill and Other Intangible Assets*. In developing assumptions about renewal or extension, FSP FAS 142-3 requires an entity to consider its own historical experience or, if it has no experience, market participant assumptions, adjusted for the entity-specific factors in paragraph 11 of SFAS 142. FSP FAS 142-3 expands the disclosure requirements of SFAS 142 and is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, with early adoption prohibited. The guidance for determining the useful life of a recognized intangible asset must be applied prospectively to intangible assets acquired after the effective date. The disclosure requirements must be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. Cornerstone does not expect the adoption of FSP FAS 142-3 to have a material impact on its financial statements.

In November 2007, the EITF issued EITF 07-01, which requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from or made to other collaborators based on other applicable generally accepted accounting principles or, in the absence of other applicable generally accepted accounting principles, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. Cornerstone does not expect the adoption of EITF 07-01 to have a material impact on its financial statements.

In June 2007, the EITF issued EITF 07-3, which concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payments should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The initial adjustment to reflect the effect of applying this EITF as a change in accounting principle is accounted for as a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. The adoption of EITF 07-03 did not have a material impact on Cornerstone's financial statements.

In December 2007, the FASB issued SFAS 141(R), which requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values

and changes other practices under SFAS 141, some of which could have a material impact on how an entity accounts for its business combinations. SFAS 141(R) also requires additional disclosure of information surrounding a business combination so that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008 and is applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009. The provisions of SFAS 141(R) will only impact Cornerstone's financial statements if Cornerstone is a party to a business combination after the effective date of the pronouncement.

In December 2007, the FASB issued SFAS 160, which requires entities to report non-controlling minority interests in subsidiaries as equity in consolidated financial statements. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. SFAS 160 is applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for presentation and disclosure requirements, which are applied retrospectively for all periods presented. Cornerstone does not expect the adoption of SFAS 160 to have a material impact on its financial statements.

In February 2007, the FASB issued SFAS 159, which permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company's choice to use fair value on its earnings. It also requires companies to display the fair value of those assets and liabilities for which they have chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Cornerstone was required to adopt SFAS 159 on January 1, 2008. The adoption of SFAS 159 did not have a material impact on Cornerstone's financial statements.

In September 2006, the FASB issued SFAS 157, which defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. In February 2008, the FASB issued FSP 157-2, which defers the effective date of applying the provisions of SFAS 157 to the fair value measurement of nonfinancial assets and nonfinancial liabilities until fiscal years beginning after November 15, 2008. Cornerstone adopted the provisions of SFAS 157 that pertain to financial assets and liabilities on January 1, 2008. The adoption of SFAS 157 did not have a material impact on Cornerstone's financial statements. Cornerstone is currently evaluating the effect FSP 157-2 will have on its financial statements.

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* — an interpretation of *FASB Statement No. 109*, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The adoption of FIN 48 did not have a material impact on Cornerstone's financial statements.

**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT  
CORNERSTONE S MARKET RISK**

Cornerstone's primary market risk exposure is related to changes in interest rates. Cornerstone does not hedge its interest rate exposure. As of March 31, 2008, Cornerstone's exposure to market risk for a change in interest rates is related solely to debt outstanding under the Paragon line of credit, which is used for working capital purposes and which bears a variable interest rate equal to the Wall Street Journal prime rate (5.00% as of June 30, 2008). At March 31, 2008, the variable rate debt outstanding that is exposed to fluctuations in the market rate of interest under the Paragon line of credit totaled \$750,000. The extent of Cornerstone's interest rate risk under this term loan is not quantifiable or predictable because of the variability of future interest rates and business financing requirements. Based on the balance outstanding at March 31, 2008, an increase in the Wall Street Journal prime rate of 100 basis points would increase Cornerstone's annualized interest expense by less than \$8,000.

## MANAGEMENT FOLLOWING THE MERGER

### Executive Officers and Directors

Upon consummation of the merger, the board of directors of the combined company will be comprised of five members classified into three classes. The following table lists the names, ages and positions of individuals currently expected to serve as directors and executive officers of the combined company upon consummation of the merger. 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.

Name	Age	Position with the Combined Company
Craig A. Collard	42	President, Chief Executive Officer and Director(1)
Chenyqua Baldwin	42	Vice President, Finance, Chief Accounting Officer and Controller
Chris Codeanne	40	Director (2)
Brian Dickson, M.D.	57	Chief Medical Officer
Michael Enright	46	Director (2)
George Esgro	47	Vice President, Sales and Marketing
Michael Heffernan	43	Director (3)
Steven M. Lutz	41	Executive Vice President, Manufacturing and Trade
Alastair McEwan	52	Director (3)

(1) Class I director, whose term will expire at the 2011 annual meeting of stockholders.

(2) Class II director, whose term will expire at the 2009 annual meeting of stockholders.

(3) Class III director, whose term will expire at the 2010 annual meeting of stockholders.

### *Executive Officers*

*Craig A. Collard* will serve as President and Chief Executive Officer of the combined company. Mr. Collard founded Cornerstone in March 2004 and has since served as its President and Chief Executive Officer and a director. Prior to Cornerstone, Mr. Collard served as the President and Chief Executive Officer of Carolina Pharmaceuticals, Inc., a company he founded in May 2003. Prior to founding Carolina Pharmaceuticals, Inc., Mr. Collard served as Vice President of Sales for Verum Pharmaceuticals Inc., or Verum, a specialty pharmaceutical company in Research Triangle Park, North Carolina from August 2002 to February 2003. From 1998 to 2002, Mr. Collard worked as Director of National Accounts at DJ Pharma, Inc., a company which was eventually purchased by Biovail Pharmaceuticals, Inc., or Biovail. His pharmaceutical career began in 1992 as a field sales representative at Dura Pharmaceuticals, Inc., or Dura. He was later promoted to several other sales and marketing positions within Dura. Mr. Collard sits on the board of directors of Hilltop Home Foundation, a Raleigh, North Carolina, non-profit corporation, in addition to the board of directors of Cornerstone. Mr. Collard holds a B.S. in Engineering from the Southern College of Technology.

*Chenyqua Baldwin* will serve as Chief Accounting Officer, Controller and Vice President of Finance of the combined company. Ms. Baldwin is a founding stockholder of Cornerstone and has served as the Vice President of Finance since August 2004. Prior to Cornerstone, Ms. Baldwin served as Vice President of Finance for Carolina Pharmaceuticals, Inc. from January 2004 to August 2004. Ms. Baldwin also held the positions of Director of Finance and Director of Accounting with Biovail Pharmaceuticals Inc., the domestic sales and marketing division of Biovail Corporation, from February 2001 to January 2004. Ms. Baldwin holds a Masters of Accounting and B.S. in Business Administration from the University of North Carolina at Chapel Hill.

*Brian Dickson, M.D.* will serve as Chief Medical Officer of the combined company. Dr. Dickson has served as the Chief Medical Officer of Cornerstone since May 2005. He joined Cornerstone after serving as the Chief Medical Officer at Inveresk Research Group Inc., or Inveresk, from May 2004 until December 2004. Prior to

Inveresk, he served as Chief Medical Officer at the contract research organization, Covalent Group Inc. (now Encorium) from 2001 to 2003. Dr. Dickson also has worked in senior management with Smith, Kline & French Laboratories Ltd. from 1978 to 1987, Searle from 1988 to 1991, and Warner Lambert / Parke Davis from 1991 to 1994. In addition to Dr. Dickson's industry experience, he is a past Editor-in-Chief of the Journal of Pharmaceutical Medicine and is a member of the Faculty of Pharmaceutical Medicine. Dr. Dickson received his Doctor of Medicine from Adelaide University in South Australia.

*George Esgro* will serve as Vice President of Sales and Marketing of the combined company. Mr. Esgro has served as Cornerstone's Vice President of Sales and Marketing since March 2008. Prior to Cornerstone, Mr. Esgro served as Regional Director for Roche Biomedical Laboratories, Inc, a network of clinical laboratories, from June 2006 to January 2008. From August 2005 to April 2006, Mr. Esgro served as the Vice President of Sales and Training for Millenium Pharmaceuticals, Inc., a biopharmaceutical company. Mr. Esgro served as Senior National Sales Director for Amgen, Inc., or Amgen, a biotechnology company, from December 2001 to August 2005. Before Amgen, Mr. Esgro held senior management and executive roles with GlaxoSmithKline from May 1988 through September 2001. Mr. Esgro holds a B.A. in Business from James Madison University.

*Steven M. Lutz* will serve as Executive Vice President of Manufacturing and Trade of the combined company. Mr. Lutz is a founding stockholder of Cornerstone and has served as Executive Vice President of Commercial Operations since March 2004. Prior to Cornerstone, Mr. Lutz served as Vice President of Corporate Accounts for Carolina Pharmaceuticals, Inc. from July 2003 to August 2004. In previous positions, Mr. Lutz was responsible for Trade Sales for Verum from September 2002 to February 2003, was a National Account Manager for Biovail from February 2001 to September 2002 and Roberts Pharmaceuticals Inc. (later acquired by Shire U.S.) from January 1995 to February 2001. Mr. Lutz holds a B.A. in Political Science and Sociology from Moravian College in Bethlehem, Pennsylvania.

### ***Directors***

*Craig A. Collard* will serve on the combined company's board of directors immediately following consummation of the merger. His biographical information is included under the heading "Executive Officers" immediately above in this proxy statement/prospectus.

*Christopher Codeanne* will serve on the combined company's board of directors immediately following consummation of the merger. Mr. Codeanne has served since April 2008 as Chief Operating Officer and Chief Financial Officer of Oncology Development Partners, LLC (d/b/a Oncopartners), a specialized international oncology contract research organization. Mr. Codeanne served as the Chief Financial Officer of Averion International Corp., a publicly-traded international contract research organization, from December 2006 through April 2008. Prior to Averion, from 2002 through July 2006, Mr. Codeanne was the Chief Financial Officer of SCIREX Corporation LLC, now Premier Research Group plc, an international, full-service clinical research organization. From 1999 to 2002, Mr. Codeanne was Director of Finance of SCIREX. Mr. Codeanne holds a B.A. in Accounting from Fairfield University and an MBA from the University of Connecticut. Mr. Codeanne is also a member of the American Institute of Certified Public Accountants, Connecticut Society of Certified Public Accountants and Financial Executives International.

*Michael Enright* will serve on the combined company's board of directors immediately following consummation of the merger. Since 1995, Mr. Enright has served as Chief Financial Officer for Atlantic Search Group, Inc., a staff augmentation and functional outsourcing services organization serving pharmaceutical companies and contract research organizations in the United States and India. Prior to 1995, Mr. Enright held positions in employee benefits administration with Hauser Insurance Group and The Prudential Insurance Company and in financial management with General Electric Company's aerospace business group. Mr. Enright holds a B.A. in Finance from Villanova University and an M.B.A. from the Kenan Flagler School of Business of University of North Carolina at Chapel Hill.

*Michael Heffernan* will serve on the combined company's board of directors immediately following consummation of the merger. Mr. Heffernan is a co-founder and has served as President and Chief Executive Officer of Collegium Pharmaceutical, Inc., or Collegium, since 2002. Collegium Pharmaceutical is a specialty



pharmaceutical company that develops and commercializes products to treat central nervous system, respiratory and skin-related disorders. Prior to Collegium Mr. Heffernan served as President and Chief Executive Officer of Clinical Studies Ltd., a pharmaceutical clinical development company, from 1995 to 1999. In previous positions, Mr. Heffernan served as President and Chief Executive Officer of PhyMatrix Corp., an integrated healthcare services company, from 1999 to 2001, and filled sales and marketing positions with Eli Lilly & Company. Mr. Heffernan also has served on the board of directors of TyRx Pharma, Inc. since 2002. Mr. Heffernan holds a B.S. in Pharmacy from the University of Connecticut and is a Registered Pharmacist.

*Alastair McEwan* will serve on the combined company's board of directors immediately following consummation of the merger. Mr. McEwan joined Cornerstone's board of directors in August 2005 and has served as Chairman of the board of directors since January 2006. From October 2005 through December 2005, Mr. McEwan acted as Cornerstone's interim Chief Financial Officer. Prior to working with Cornerstone, Mr. McEwan was a Group Executive Vice President of Inveresk Research Group, Inc. and served as President of Inveresk Global Clinical Operations beginning in 2003. He had previously been President of Inveresk Clinical Americas operations beginning in April 2001. From January 2000 until March 2001, Mr. McEwan was Head of Corporate Development of Inveresk Research Group focusing on mergers and acquisitions, and served as General Manager, Clinical, of Inveresk Research Group Limited from June 1996 until December 1999. Mr. McEwan served as a member of the Group Executive Board of Inveresk Research Group, Inc. from 1999 to 2004. Mr. McEwan sits on the board of Averion International Corp., a publicly-traded international contract research organization, in addition to the board of Cornerstone. Mr. McEwan qualified as a Chartered Accountant in 1979 with the Institute of Chartered Accountants of Scotland and holds a Bachelor of Commerce from the University of Edinburgh.

## **The Board of Directors**

### ***Board Composition***

The combined company's board of directors will initially be composed of five directors, three of whom will be independent of management. The terms of office of the directors will be divided into three classes:

Class I, whose term will expire at the 2011 annual meeting of stockholders;

Class II, whose term will expire at the 2009 annual meeting of stockholders; and

Class III, whose term will expire at the 2010 annual meeting of stockholders.

Upon the consummation of the merger, Class I will consist of Mr. Collard, Class II will consist of Mr. Codeanne and Mr. Enright, and Class III will consist of Mr. McEwan and Mr. Heffernan. Pursuant to the bylaws of Critical Therapeutics, the board of directors may appoint from its members a Chairman. Mr. Collard is expected to be appointed as Chairman of the board of directors. In that case, because the Chairman of board of directors will not be an independent director, Cornerstone expects that the board of directors will designate a Lead Independent Director at the first meeting of the board of directors. The Lead Independent Director will be responsible for presiding over the executive sessions of the independent directors, ensuring proper information flow to all outside directors, and any other functions that may be specified to the position.

### ***Board Committees***

The combined company will have an audit committee, a compensation committee and a nominating and corporate governance committee. The members of each committee will be appointed by the combined company's board of directors, upon recommendation of the nominating and corporate governance committee, and serve one-year terms.

Each of these committees will operate under a charter that has been approved by the board of directors.

*The Audit Committee*

The Audit Committee's responsibilities will include:

appointing, approving the compensation of, and assessing the independence of the combined company's registered public accounting firm;

overseeing the work of the combined company's independent registered public accounting firm, including through the receipt and consideration of reports from the independent registered public accounting firm;

reviewing and discussing with management and the independent registered public accounting firm the combined company's annual and quarterly financial statements and related disclosures;

monitoring the combined company's internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;

establishing policies regarding hiring employees from the independent registered public accounting firm and procedures for the receipt and retention of accounting-related complaints and concerns;

meeting independently with the combined company's independent registered public accounting firm and management to discuss the combined company's financial statements, and other financial reporting and audit matters;

preparing the audit committee report required by SEC rules; and

reviewing and approving or ratifying related person transactions.

The members of the Audit Committee will be Mr. Codeanne, Mr. Enright and Mr. Heffernan. Mr. Codeanne will serve as chair of the Audit Committee. Cornerstone expects that the combined company board of directors will determine that Mr. Codeanne is an audit committee financial expert as defined by applicable SEC rules.

*The Compensation Committee*

The Compensation Committee's responsibilities will include:

reviewing and making recommendations to the board of directors regarding the compensation of the combined company's executive officers;

overseeing the evaluation of the combined company's senior executives;

reviewing and making recommendations to the board of directors regarding incentive compensation and equity-based plans;

administering the combined company's stock incentive plans;

reviewing and making recommendations to the board of directors regarding director compensation;

reviewing and discussing with management the combined company's Compensation Discussion and Analysis; and

preparing the compensation committee report required by SEC rules.

The members of the Compensation Committee will be Mr. Heffernan and Mr. Enright. Mr. Heffernan will serve as chair of the Compensation Committee.

*The Nominating and Corporate Governance Committee*

The Nominating and Corporate Governance Committee's responsibilities will include:

identifying individuals qualified to become board members;

recommending to the board of directors the persons to be nominated for election as directors and to each of the board of director's committees;

reviewing and making recommendations to the board of directors with respect to management succession planning;

developing and recommending to the board of directors corporate governance principles; and

overseeing an annual evaluation of the board of directors.

The members of the Nominating and Corporate Governance Committee will be Mr. Enright and Mr. Codeanne. Mr. Enright will serve as chair of the Nominating and Corporate Governance Committee.

### ***Compensation of Directors***

The policy of the combined company with respect to the compensation of directors is expected to be determined at the first meeting of the board of directors following the consummation of the merger.

### **Certain Relationships and Related Transactions, and Director Independence**

#### ***Transactions with Related Persons***

#### ***Employment and Related Agreements***

Cornerstone has entered into employment and related agreements with certain of its executive officers. For more information regarding these employment agreements, please see the section **Interests of Cornerstone's Executive Officers and Directors in the Merger** **Employment and Related Agreements** beginning on page 106 of this proxy statement/prospectus.

#### ***Consulting Arrangement with Mr. McEwan***

In addition to serving as a director, Mr. McEwan has served as a consultant providing strategic, management, financial and corporate governance advice to Cornerstone. In connection with his service as a consultant in 2007, Mr. McEwan received \$30,000 in cash compensation and \$12,813 in benefits including health insurance, life insurance and long-term disability insurance.

#### ***Other Related Party Transactions***

In April 2004, Cornerstone entered into the Carolina Note, an unsecured loan agreement with Carolina Pharmaceuticals, whereby Cornerstone could borrow up to \$15.0 million at 10% interest for five years. Because Mr. Collard owns over 50% of the voting shares of Carolina Pharmaceuticals, he is a control person of Carolina Pharmaceuticals. Cornerstone borrowed \$13.0 million under the Carolina Note in April 2004. In June 2006, Cornerstone entered into a note amendment and waiver agreement that provided for the offset of approximately \$3.6 million in principal and \$1.8 million in accrued interest outstanding under the Carolina Note against equal amounts due to Cornerstone from Cornerstone Biopharma Holdings, Ltd. and Carolina Pharmaceuticals. The amounts due to Cornerstone primarily resulted from the 2005 Adams litigation settlement. As of December 31, 2007 and 2006, approximately \$9.4 million in principal was outstanding under the Carolina Note plus approximately \$549,000 and \$1.5 million in accrued interest, respectively. On April 11, 2008, Cornerstone made a principal payment of \$460,000 on the Carolina Note. The outstanding principal and accrued interest are due in 2009. At June 30, 2008, the outstanding principal amount of the Carolina Note was approximately \$9.0 million.

Carolina Pharmaceuticals, which is the holder of the Carolina Note, has entered into an agreement that provides, among other things, for the exchange or conversion of the outstanding principal amount of the Carolina Note into shares of Cornerstone's common stock prior to the effective time of the merger and for the same voting and lock-up provisions provided pursuant to the agreements entered into by Cornerstone's other stockholders.

From time to time, Mr. Collard has been provided with certain salary advances from Cornerstone. Since January 1, 2005, the total amount of such advances has been \$2.7 million. As of July 14, 2008, Mr. Collard has no outstanding salary advances from Cornerstone, and no such advances will be made in the future.

### ***Review, Approval or Ratification of Transactions with Related Persons***

The policies and procedures of the combined company for the review, approval, or ratification of related-party transactions will be determined prior to the consummation of the merger.

### ***Director Independence***

Under applicable NASDAQ rules, a director will only qualify as an independent director if, in the opinion of Critical Therapeutics board of directors, that person does not have a relationship which would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In connection with the consummation of the merger, the incumbent directors of the Critical Therapeutics board of directors will fix the size of the board at five directors, tender their resignations effective as of the effective time of the merger and simultaneously appoint Messrs. Collard, McEwan, Codeanne, Enright and Heffernan to fill the vacancies created by such resignations. Prior to appointing Messrs. Codeanne, Enright and Heffernan to the Critical Therapeutics board of directors, the incumbent directors will determine whether Messrs. Codeanne, Enright and Heffernan are independent as defined under NASDAQ rules. Additionally, the incumbent directors of Critical Therapeutics will determine whether those individuals meet the additional independence requirements of Rule 10A-3 under the Securities Exchange Act of 1934. Finally, the incumbent directors of Critical Therapeutics will determine whether all of the members of each of the board of directors three standing committees will be independent as defined under NASDAQ rules. If Critical Therapeutics board of directors determines that any of Messrs. Codeanne, Enright and Heffernan is not independent as defined under NASDAQ rules or does not meet the additional independence requirements of Rule 10A-3 under the Securities Act, Cornerstone would withdraw the nomination of such individual and instead would nominate another individual that is independent under those rules.

### ***Executive Compensation and Other Information***

The following discussion and tables set forth information with regard to compensation for services rendered in all capacities to Cornerstone and its subsidiaries during the fiscal year ended December 31, 2007, by officers of Cornerstone who are expected to serve as executive officers of the combined company following the consummation of the merger.

### ***Compensation Discussion and Analysis***

Following the consummation of the merger, Cornerstone anticipates that each of Mr. Collard, Ms. Baldwin, Dr. Dickson, Mr. Esgro and Mr. Lutz will serve as an executive officer of the combined company. Each of these individuals currently serves as an executive officer of Cornerstone. Compensation decisions with respect to these Cornerstone executive officers have historically been based on the objective of attracting and retaining individuals who can help Cornerstone meet and exceed its financial and operational goals. Cornerstone generally considers the growth of the company, individual performance and market trends in setting individual compensation levels for its executive officers. Cornerstone provides both cash and equity-based compensation, with the goal of the latter being to align the interests of Cornerstone's executive officers with the interest of Cornerstone's stockholders and incentivize the executive officers to achieve long-term growth for Cornerstone. Cornerstone currently awards equity-based compensation to its executive officers on an entirely discretionary basis.

*Determination of Compensation*

For fiscal year 2007, Cornerstone did not have a compensation committee and all compensation decisions regarding Cornerstone's executive officers were made by Cornerstone's board of directors. The board of directors received compensation recommendations for the executive officers from the Chief Executive Officer.



These recommendations were based on the executive officer's achievement of individual performance goals and the results of the individual performance evaluation process. Cornerstone's board of directors reviewed these recommendations, proposed adjustments and, subject to any reviews it deemed appropriate, approved the compensation packages for its executive officers. The board of directors also considered certain subjective factors in determining an executive's compensation, including, but not limited to, the executive's contribution to achievement of Cornerstone's financial goals, the executive officer's management ability and whether the executive officer's total compensation was competitive in the market given the executive officer's responsibilities.

#### *Components of Compensation for Fiscal Year 2007*

For fiscal year 2007, the compensation provided to Cornerstone's executive officers who will become executive officers of the combined company following the consummation of the merger consisted of base salary, annual bonus and equity-based compensation, each of which is described in more detail below.

#### **Base Salary**

The base salary payable to each of Cornerstone's executive officers is intended to provide a fixed component of compensation reflecting the executive officer's skill set, experience, role and responsibilities. Additionally, Cornerstone's board of directors intended for the salary paid to each of the executive officers to be competitive within the Raleigh/Durham, North Carolina geographic area where Cornerstone is headquartered, within the pharmaceutical industry as a whole and with companies with a comparable volume of general sales. Minimum base salaries are set forth in each of the executive officer's employment agreements, the terms of which are set forth in the section Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table beginning on page 265 of this proxy statement/prospectus. The determination of Cornerstone's board of directors as to whether an increase in base salary is merited for any executive officer during any particular year depends on the individual's performance during the prior year, Cornerstone's performance during the prior year and on competitive market practices.

For fiscal 2007, base salaries generally accounted for 65% of each executive officer's total compensation. The following table sets forth annual base salary rates in effect at the end of fiscal 2006 and fiscal 2007 for each of the executive officers, as well as percentage increases from 2006 to 2007:

<b>Name</b>	<b>Fiscal 2006</b>	<b>Fiscal 2007</b>	<b>Percent Increase</b>
Craig A. Collard	\$ 295,697	\$ 365,000	23%
Chenyqua Baldwin	\$ 166,278	\$ 215,000	29%
Brian Dickson, M.D.	\$ 239,787	\$ 260,000	8%
George Esgro	N/A	N/A	N/A
Steven M. Lutz	\$ 204,000	\$ 204,000	

Mr. Collard's base salary increase from fiscal 2006 to fiscal 2007 was 23%. In determining this increase, Cornerstone's board of directors considered the percentage salary increases received by all other Cornerstone employees during the period. Mr. Collard was then provided with an increase equivalent to the average percentage salary increase received by all other employees.

Ms. Baldwin's base salary increase from fiscal 2006 to fiscal 2007 was 29%. In determining this increase, Cornerstone's board of directors considered Ms. Baldwin's salary in relation to her experience, and her achievement of

her 2006 performance goals which included: achievement of Cornerstone's net revenue targets, maintaining the Finance Department's budget within targeted levels, maintaining Cornerstone's budget within targeted levels, effectively managing Cornerstone's relationship with its independent auditors, effectively documenting Cornerstone's policies and procedures, effectively assisting Cornerstone's legal team, and effectively completing the financial planning, analysis and modeling related to investor presentations.

Dr. Dickson's base salary increase from fiscal 2006 to fiscal 2007 was 8%. Cornerstone's board of directors considered Dr. Dickson's salary compared to similar positions at peer companies, and his achievement of his

2006 performance goals, which included: preparing and submitting FDA applications relating to Cornerstone's products, directing the negotiations to acquire additional products, effectively assisting the legal team, effectively working with the manufacturers of Cornerstone's products, filing on time all required reports related to Cornerstone's products with the FDA, and effectively developing Cornerstone's product portfolio.

#### *Annual Bonuses*

Annual bonuses are intended to link Cornerstone's strategic and corporate operating plans with individual performance, and to provide executive officers with incentives to achieve greater corporate performance by focusing on the attainment of specific goals. The target bonus awards for executive officers is based on a percentage of annual base salary, and is set at 50% of base salary for the Chief Executive Officer, and 35% of base salary for all other executive officers.

In determining the amount of the annual bonus for each executive officer, Cornerstone's board of directors considered the executive officer's achievement of individual goals established on a quarterly basis. At the beginning of each quarter, the Chief Executive Officer establishes individual quarterly goals for each executive officer, and these goals are provided to the executive officer in writing. These goals are tailored to the specific duties and responsibilities of each executive officer and are intended to focus the executive officers on achieving short-term objectives within their specific area of responsibility. Typically, the Chief Executive Officer meets with each executive officer on a monthly basis to track the progress of the individual's quarterly goals.

Bonuses are paid to executive officers on an annual basis following completion of Cornerstone's audit. In order to be eligible to receive an annual bonus, the executive officer must be an employee of Cornerstone at the time of the completion of the audit. With the exception of Mr. Collard, executive officers whose employment is terminated prior to the completion of the audit will not receive any bonus payment for the prior fiscal year, regardless of whether such executive officer was employed by Cornerstone at the end of the fiscal year. Under his Executive Retention Agreement, described in the section Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table Employment and Related Agreements beginning on page 265 of this proxy statement/prospectus, Mr. Collard would be entitled to receive certain annual bonus payments for the fiscal year under certain circumstances in the event his employment is terminated in connection with a change in control prior to the completion of Cornerstone's audit.

The following chart shows bonuses received in fiscal 2006 and fiscal 2007 for each of the executive officers, as well as percentage increases from 2006 to 2007:

<b>Name</b>	<b>Fiscal 2006</b>	<b>Fiscal 2007</b>	<b>Percent Increase</b>
Craig A. Collard	\$ 147,849	\$ 182,500	23.4%
Chenyqua Baldwin	\$ 58,197	\$ 75,250	29.3%
Brian Dickson, M.D.	\$ 83,925	\$ 91,000	8.4%
George Esgro	N/A	N/A	N/A
Steven M. Lutz	\$ 71,400	\$ 87,500	22.5%

#### *Equity Compensation*

Cornerstone's equity compensation awards are designed to align the interests of Cornerstone's executive officers with the interests of Cornerstone's stockholders by providing the executive officers with equity ownership opportunities and

performance-based incentives. In fiscal 2007, all equity awards by Cornerstone were in the form of stock options.

While Cornerstone encourages its executive officers to own substantial equity of the company, equity grants have historically been made to the executive officer at the time the officer joins Cornerstone, rather than as a component of annual compensation. Any additional equity grants to executive officers are made on an entirely

discretionary basis by the board of directors and are based on subjective factors including, but not limited to, the individual's contribution to Cornerstone and the individual's total holdings of the equity of Cornerstone.

All of the equity compensation awards granted in fiscal 2007 were granted under Cornerstone's 2005 Stock Incentive Plan. The stock options awarded in fiscal 2007 will vest in 25% increments on the anniversary of the date of the grant in 2008, 2009, 2010 and 2011.

#### *Perquisites and Other Benefits*

Cornerstone has provided perquisites to its executive officers as a means of providing additional compensation to the executive officers, through the availability of benefits that are convenient for the executives to use when faced with the demands of their positions. These perquisites included the use of company cars or automobile allowances, and in the case of Cornerstone's Chief Executive Officer, a country club membership.

In addition, Cornerstone's executive officers, like other employees, are entitled to participate in Cornerstone's employee benefit plans including medical insurance, dental insurance, vision insurance, life insurance, long-term disability insurance and a 401(k) savings plan. Cornerstone's executive officers, unlike other employees, are not required to make any payments or other contributions in order to participate in the medical insurance, dental insurance or vision insurance plans.

#### *Severance Benefits*

Cornerstone's executive officers are entitled to receive severance benefits upon qualifying terminations of employment, pursuant to provisions in each executive's employment agreement or executive retention agreement, and the terms of the 2005 Stock Incentive Plan. These severance arrangements are primarily intended to retain the executive officers, as the executive officers will forego the right to receive a significant payment if they voluntarily terminate their employment without good reason. For a more complete description of these severance arrangements, please see the section "Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table" beginning on page 265 of this proxy statement/prospectus, and the section "Potential Payments upon Termination or Change in Control" beginning on page 271 of this proxy statement/prospectus.

#### *Summary Compensation Table*

Name and Principal Position	Year	Salary (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation		Total (\$)
				(\$)(1)	All Other Compensation (\$)	
Craig A. Collard President and Chief Executive Officer	2007	365,000	53,968	182,500	59,469(2)	660,937
Chenyqua Baldwin Vice President, Finance	2007	215,000	41,262	75,250	26,411(3)	357,923
Brian Dickson, M.D. Chief Medical Officer	2007	260,000	52,261	91,000	25,238(4)	428,499
George Esgro(5)	2007	N/A	N/A	N/A	N/A	N/A

Vice President, Sales and  
Marketing

Steven M. Lutz	2007	204,000	42,834	87,500	28,064(6)	362,398
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Executive Vice President,  
Manufacturing and Trade

(1) This column reflects annual bonuses for 2007 as described in the section Compensation Discussion and Analysis Annual Bonuses beginning on page 263 of this proxy statement/prospectus.

- (2) Represents \$33,025 and \$14,515 in automobile payments in 2007 for company cars for personal use by Mr. Collard and his spouse, respectively, \$8,726 in country club membership payments in 2007 and \$3,203 in additional payments for employee benefit plans in 2007.
- (3) Represents \$24,395 in automobile payments in 2007 and \$2,016 in additional payments for employee benefit plans in 2007.
- (4) Represents \$22,035 in automobile payments in 2007 and \$3,203 in additional payments for employee benefit plans in 2007.
- (5) Mr. Esgro was not employed by Cornerstone during fiscal 2007.
- (6) Represents \$24,995 in automobile payments in 2007 and \$3,069 in additional payments for employee benefit plans in 2007.

### ***2007 Grants of Plan-Based Awards***

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards(1)			All Other Option Awards: Number of Securities	Exercise or Base Price of Option Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards (\$)
		Threshold (\$)	Target (\$)	Maximum (\$)	Underlying Options (#)	Awards	
Craig A. Collard	3/16/2007		182,500		1,000,000	0.42	270,000
Chenyqua Baldwin	3/16/2007		72,250		750,000	0.42	202,500
Brian Dickson, M.D.	3/16/2007		91,000		750,000	0.42	202,500
George Esgro			N/A				
Steven M. Lutz	3/16/2007		80,500(2)		750,000	0.42	202,500

- (1) These columns reflect the targeted amounts of the annual bonuses for 2007 as described in the section Compensation Discussion and Analysis Annual Bonuses beginning on page 263 of this proxy statement/prospectus.
- (2) Equal to 35% of \$230,000, the 2007 salary that Cornerstone's board of directors approved for Mr. Lutz on March 16, 2007.

*Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table*

*Employment and Related Agreements*

*Chief Executive Officer Employment and Related Agreements*

On March 1, 2006, Cornerstone entered into an employment agreement with Mr. Collard, pursuant to which he serves as the President and Chief Executive Officer of Cornerstone. The initial term of the employment agreement continued until December 31, 2006, with automatic renewal for additional one-year terms unless the agreement is terminated or either party gives notice of non-renewal at least 60 days prior to the end of the then current term. The current renewal term of the agreement continues until December 31, 2008. Under the terms of the agreement, Mr. Collard is entitled to an annual salary, which may be increased from time to time by the board of directors. If Cornerstone terminates Mr. Collard's agreement other than because of his death or disability, the liquidation, dissolution or discontinuance of business by Cornerstone, or for cause, and if Mr. Collard executes a release and settlement agreement, he will be entitled to:

a lump sum payment in an amount equal to 12 months of base salary, payable 30 days after the termination, and



continuation of benefits for the shorter of 12 months, or until Mr. Collard obtains reasonably comparable benefits coverage from another employer.

Upon termination of Mr. Collard's employment, Cornerstone will pay, or reimburse, Mr. Collard for the balance of the remaining lease payments on the vehicle provided by Cornerstone for his use, and will assign and transfer title and other appropriate evidence of ownership of the vehicle to Mr. Collard.

On February 8, 2006, Cornerstone and Mr. Collard entered into an Executive Retention Agreement that provides for severance benefits under specified circumstances following a change in control. In the event that Mr. Collard's employment is terminated within 24 months following a change in control either by Cornerstone without cause, or by Mr. Collard for good reason, Mr. Collard would be entitled to receive a lump sum payment consisting of:

accrued but unpaid base salary, bonus (calculated using Mr. Collard's annual bonus paid or payable for the then most recently completed fiscal year) and vacation days; and

an amount equal to two times the sum of (1) Mr. Collard's highest annual base salary during the three-year period prior to the change in control and (2) Mr. Collard's highest annual bonus during the three-year period prior to the change in control.

Any stock options then held by Mr. Collard will also become immediately exercisable in full, and each outstanding restricted stock award will become fully vested and no longer subject to a right of repurchase by Cornerstone. The Executive Retention Agreement also provides that, upon such a termination, Mr. Collard will be entitled to 24 months of continuing benefits, or until he receives comparable benefits from another employer. In the event that Mr. Collard resigns without good reason or is terminated due to his death or disability, he would be entitled to receive accrued but unpaid base salary, bonus and vacation days. In the event that Mr. Collard is terminated by Cornerstone for cause, he would be entitled to receive a lump sum payment consisting of accrued but unpaid base salary.

On March 1, 2006, Mr. Collard and Cornerstone entered into a Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement. Pursuant to this agreement, Mr. Collard agreed not to compete with Cornerstone during the term of his employment and for a period of one year following his termination. Mr. Collard also agreed to a provision that prohibits him from soliciting, among others, Cornerstone's employees and customers during the term of his employment and for one year following termination of employment. The agreement also contains customary confidentiality provisions, and provisions relating to the assignment of inventions.

***Employment and Related Agreements with Other Executive Officers Who Will Become Executive Officers of the Combined Company***

Cornerstone is currently a party to employment agreements with Ms. Baldwin, Dr. Dickson and Mr. Lutz. Pursuant to these employment agreements, each of Ms. Baldwin, Dr. Dickson and Mr. Lutz serves as an executive officer of Cornerstone. The initial term of Ms. Baldwin's, Dr. Dickson's and Mr. Lutz's employment agreements continued until December 31, 2006, with automatic renewal for additional one-year terms unless the agreement is terminated or either party gives notice of non-renewal at least 60 days prior to the end of the term. The current renewal term of each agreement continues until December 31, 2008. Each executive officer is entitled to a minimum base salary and is eligible to receive an annual bonus as determined by Cornerstone's board of directors. If Cornerstone terminates Ms. Baldwin's, Mr. Dickson's or Mr. Lutz's agreement other than because of the executive officer's death or disability, the liquidation, dissolution or discontinuance of business by Cornerstone or for cause, and if the executive officer executes a release and settlement agreement, the executive officer will be entitled to:

a lump sum payment in an amount equal to three months of base salary (six months in the case of Mr. Lutz), payable 30 days after the termination, and

continuation of benefits for the shorter of three months (six months in the case of Mr. Lutz), or until the executive officer obtains reasonably comparable benefits coverage from another employer.

Upon termination of Mr. Lutz's employment, Cornerstone will pay, or reimburse, Mr. Lutz for the balance of the remaining lease payments on the vehicle provided by Cornerstone for his use, and will assign and transfer title and other appropriate evidence of ownership of the vehicle to Mr. Lutz.

Ms. Baldwin, Dr. Dickson, and Mr. Lutz each entered into Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreements, which contain non-compete, non-solicit, invention assignment, and confidentiality provisions, which are identical to those contained in Mr. Collard's Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement.

Mr. Esgro has also entered into an employment agreement with Cornerstone. Mr. Esgro's agreement is for an indefinite term, terminable either by Mr. Esgro or Cornerstone at any time. Mr. Esgro's agreement does not provide for severance payment in the event of his termination. In the event of a change in control of Cornerstone, Mr. Esgro's employment agreement provides that any rights in Cornerstone's stock, stock options, benefits or otherwise that are unvested and would have become vested through the passage of time will immediately vest. For purposes of Mr. Esgro's employment agreement only, a change in control is defined as the transfer of greater than 50% of the common ownership of Cornerstone to an unrelated third party. Mr. Esgro's employment agreement prohibits him from competing with Cornerstone during the term of his employment and for one year thereafter, and also contains standard non-solicit, confidentiality and invention assignment provisions.

### *Definitions*

For purposes of Mr. Collard's Executive Retention Agreement and each of Ms. Baldwin's, Mr. Dickson's and Mr. Lutz's respective employment agreements, the terms below have the following meanings:

change in control means either one or more of the events or occurrences set below:

an acquisition of ownership of stock of Cornerstone by any one person or group that, together with stock previously held by such person or group, constitutes more than 50% of the total fair market value or total voting power of the stock of Cornerstone; provided however, that the following acquisitions are not a change in control: (i) any acquisition of ownership of stock of Cornerstone for the primary purpose of a debt or equity financing of Cornerstone; or (ii) the acquisition of any stock of Cornerstone by any person that is a stockholder of Cornerstone on February 8, 2006; or (iii) any acquisition in which Cornerstone becomes a subsidiary of another corporation and in which the stockholders of Cornerstone immediately prior to the transaction will own, immediately after the transaction, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the parent corporation would be entitled in the election of directors; and

an acquisition by any one person, or more than one person acting as a group, of assets of Cornerstone that have a total gross fair market value equal to or more than 90% of the total gross fair market value of all of the assets of Cornerstone immediately prior to the acquisition; provided, however, that any acquisition of any assets of Cornerstone by any person or group that was a stockholder of Cornerstone on February 8, 2006 does not constitute a change in control.

cause or for cause means:

breach of the executive officer's employment agreement or failure to diligently and properly perform his or her duties;

misappropriation or unauthorized use of Cornerstone's property or breach of his or her Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement;

failure to comply with Cornerstone's policies and/or directives of the board of directors;

use of illegal drugs or any illegal substance, or the use of alcohol in a manner detrimental to the performance of duties;

dishonest or illegal action that is detrimental to Cornerstone;

failure to fully disclose material conflicts of interest;

any adverse action or omission that would be required to be disclosed pursuant to public securities laws or that would limit the ability of Cornerstone or any entity affiliated with Cornerstone to sell securities or cause Cornerstone to be disqualified from an exemption otherwise available; or

violation of Cornerstone's policies prohibiting harassment, unlawful discrimination, retaliation or workplace violence.

good reason means the occurrence, without the executive officer's written consent, of any of the events or circumstances below:

the assignment of duties inconsistent with the officer's position

reduction in annual base salary

failure to: (i) continue material compensation or benefit plans or programs, (ii) continue the executive officer's participation in such plans, or (iii) award bonuses to the executive officer substantially consistent with past practice.

requiring the executive officer to be based more than 50 miles from his or her location immediately prior to the change in control, or requiring the executive officer to travel on business to a substantially greater extent than immediately prior to the change in control.

Cornerstone's failure to obtain a satisfactory agreement from any successor to assume and agree to perform the agreement; or

the failure of Cornerstone to pay or provide to the executive officer any portion of his compensation or benefits due within 10 days of being due, or any material breach of the executive officer's employment agreement or Executive Retention Agreement.

#### *2005 Stock Incentive Plan*

On December 23, 2005, Cornerstone's board of directors adopted the 2005 Stock Incentive Plan pursuant to which awards may be made under the plan for up to 10,000,000 shares of Cornerstone's common stock. The plan permits Cornerstone's board of directors to grant awards, including stock options and restricted stock, to participants. Cornerstone's board may establish vesting and performance requirements for any grant. Cornerstone's board of directors may amend or terminate the 2005 Stock Incentive Plan at any time. Historically, most grants of equity securities under the 2005 Stock Incentive Plan have been in the form of stock options.

Stock option grants awarded under the 2005 Stock Incentive Plan are subject to adjustments in the event of a change in Cornerstone's capitalization, liquidation, dissolution, reorganization or change in control.

In the event of a change in Cornerstone's capitalization, such as a stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any distribution to holders of Cornerstone's common stock other than an ordinary cash dividend, the board of directors may adjust the terms of option grants, including the number and class of securities and exercise price per share of each outstanding option.

In the event of a proposed liquidation or dissolution of Cornerstone, the plan requires the board of directors, upon written notice to the plan participants, to provide that all then unexercised options will become exercisable in full as of a specified time at least 10 business days prior to the effective date of such liquidation or dissolution and terminate effective upon such liquidation or dissolution, except to the extent exercised before such effective date.

Upon the occurrence of a reorganization event of Cornerstone, the plan requires that the board of directors shall provide that all outstanding options shall be assumed, or equivalent options shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof); provided that if such reorganization event also constitutes a change in control event, such assumed or substituted options shall become immediately

exercisable in full if, on or prior to the twelve-month anniversary of the date of the consummation of the reorganization event, the plan participant's employment with Cornerstone or the acquiring or succeeding corporation is terminated for good reason by the plan participant or is terminated without cause by Cornerstone or the acquiring or succeeding corporation.

Upon the occurrence of a change in control event that does not also constitute a reorganization event, each then-outstanding option shall continue to become vested in accordance with the original vesting schedule set forth in such option; provided, however, that each such option shall become immediately exercisable in full if, on or prior to the twelve-month anniversary of the date of the consummation of the change in control event, the plan participant's employment with Cornerstone or the acquiring or succeeding corporation is terminated for good reason by the Participant or is terminated without cause by Cornerstone or the acquiring or succeeding corporation.

### ***Definitions***

For purposes of the 2005 Stock Incentive Plan, the terms below have the following meanings:

A reorganization event means:

any merger or consolidation of Cornerstone with or into another entity as a result of which all of the common stock of Cornerstone is converted into or exchanged for the right to receive cash, securities or other property; or

any exchange of all of the common stock of Cornerstone for cash, securities or other property pursuant to a share exchange transaction.

A change in control event means:

the acquisition by any person (which could be an individual, entity or group) of more than 50% of the outstanding common stock or voting securities of Cornerstone, except for acquisitions directly from Cornerstone or in connection with certain mergers or consolidations;

a majority of Cornerstone's board is replaced by directors who are not elected or recommended for election by Cornerstone's board; or

Cornerstone consummates certain mergers or consolidations.

good reason means:

a significant diminution in the plan participant's title, authority or responsibilities;

reduction in annual cash compensation; or

relocation of the plan participant's place of business more than 50 miles from the current site.

cause means:

willful failure by the plan participant to perform his or her material responsibilities; or

willful misconduct by the plan participant that affects the business reputation of Cornerstone.

*Stock Option Grants*

As reported in the section "2007 Grants of Plan Based-Awards" beginning on page 265 of this proxy statement/prospectus, Cornerstone granted stock options to its executive officers on March 16, 2007. These stock options awards will vest in 25% increments on the anniversary of the date of the grant in 2008, 2009, 2010 and 2011.



*2007 Outstanding Equity Awards at Fiscal Year-End*

Name	Number of Securities	OPTION AWARDS (1)			STOCK AWARDS	
		Number of Securities	Number of Securities	Option	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)
	Underlying Unexercised Options (#) Exercisable	Underlying Unexercised Options (#) Unexercisable	Exercise Price (\$/Sh)	Option Expiration Date		
Craig A. Collard	50,000(2)		\$ 0.10	8/1/2015		
		1,000,000	\$ 0.42	3/16/2017		
Chenyqua Baldwin	12,500	37,500	\$ 0.10	2/23/2016		
		750,000	\$ 0.42	3/16/2017		
					187,500(3)	(4)
Brian Dickson, M.D.	206,250(5)	68,750	\$ 0.10	5/9/2015		
	75,000(6)	75,000	\$ 0.10	8/1/2015		
	81,250(7)	243,750	\$ 0.10	8/1/2015		
		750,000	\$ 0.42	3/16/2017		
George Esgro(8)						
Steven Lutz	18,750	6,250(9)	\$ 0.25	7/1/2015		
	37,500	112,500	\$ 0.10	2/23/2016		
		750,000	\$ 0.42	3/16/2017		

(1) Except as otherwise noted, the option awards reflected in these columns will vest in 25% increments on each of the first, second, third, and fourth anniversary of the date of the grant. The date of grant for each of these options is the date 10 years prior to the expiration date reflected in this table.

(2) Option award vested immediately on January 17, 2006, the date of grant.

(3) The vesting schedule for this restricted stock award is 25% on July 13, 2005, 25% on July 13, 2006, 25% on July 13, 2007 and 25% on July 13, 2008.

(4) Cornerstone is a private company and no public market exists for its common stock.

(5) The vesting schedule for this option award is 25% on December 1, 2005, 25% on December 1, 2006, 25% on December 1, 2007, and 25% on December 1, 2008. The date of grant for this award was January 17, 2006.

(6) The vesting schedule for this option award is 25% on August 1, 2006, 25% on August 1, 2007, 25% on August 1, 2008 and 25% on August 1, 2009. The date of grant for this award was January 17, 2006.

- (7) The vesting schedule for this option award is 25% on February 9, 2007, 25% on February 9, 2008, 25% on February 9, 2009, and 25% on February 9, 2010. The date of grant for this award was February 8, 2006.
- (8) Mr. Esgro was not employed by Cornerstone on December 31, 2007.
- (9) The vesting schedule for this option award is 25% on December 1, 2005, 25% on December 1, 2006, 25% on December 1, 2007 and 25% on December 1, 2008. The date of grant for this award was July 1, 2005.

**2007 Option Exercises and Stock Vested**

Name	OPTION AWARDS		STOCK AWARDS	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting (\$)
Craig A. Collard				
Chenyqua Baldwin			187,500	(1)
Brian Dickson, M.D.				
George Esgro				
Steven M. Lutz				

(1) Cornerstone is a private company and no public market exists for its common stock.

(2) Mr. Esgro was not employed by Cornerstone on December 31, 2007.

**Potential Payments upon Termination or Change in Control**

Cornerstone has entered into employment and/or retention agreements with each of its executive officers. These agreements provide for payments and benefits to the executive officer upon termination of employment or a change of control of Cornerstone under specified circumstances. In addition, the 2005 Equity Incentive Plan provides for accelerated vesting of equity awards under specified circumstances following a change in control. For information regarding the specific circumstances that would trigger payments and the provision of benefits, the manner in which payments and benefits would be provided and conditions applicable to the receipt of payments and benefits, see Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table beginning on page 265 of this proxy statement/prospectus.

The following tables set forth information regarding potential payments and benefits that each executive officer would receive upon termination of employment or a change of control of Cornerstone under specified circumstances, assuming that the triggering event in question occurred on December 31, 2007, the last business day of the fiscal year.

Name	Termination without Cause Prior to		Any Termination of Employment Other
	Cash Payments	Value of Benefits	
Craig A. Collard	\$ 365,000	\$ 12,813	\$ 87,277(1)
Chenyqua Baldwin	\$ 53,750	\$ 2,016	
Brian Dickson, M.D.	\$ 65,000	\$ 3,204	
George Esgro(2)			

Steven M. Lutz	\$	102,000	\$	6,138	\$	38,651(1)
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- (1) Payment reflects that upon termination of the executive officer's employment, Cornerstone will pay, or reimburse, the executive officer for the balance of the remaining lease payments on the vehicle provided by Cornerstone for the executive officer's use, and will assign and transfer title and other appropriate evidence of ownership of the vehicle to the executive officer. These payments are in addition to any other payments the executive officer would receive in connection with a termination of employment.
- (2) Mr. Esgro was not employed by Cornerstone on December 31, 2007.

Name	Termination without Cause or for Good Reason in Connection with a Change in Control			Voluntary		
	Cash Payments	Value of Benefits	Value of Options with Accelerated Vesting	Value of Stock with Accelerated Vesting	Resignation Following a Change in Control Cash Payments	Death/Disability Following a Change in Control Cash Payments
Craig A. Collard	\$ 1,242,849	\$ 25,626	\$ 213,750(1)(2)		\$ 147,849	\$ 147,849
Chenyqua Baldwin	\$ 53,750	\$ 2,016	\$ 160,313(2)(3)	(4)		
Brian Dickson, M.D.	\$ 65,000	\$ 3,204	\$ 170,469(2)(3)			
George Esgro(5)						
Steven M. Lutz	\$ 102,000	\$ 6,138	\$ 165,001(2)(3)			

- (1) Mr. Collard's Executive Retention Agreement provides that in the event that his employment is terminated within 24 months following a change in control either by Cornerstone without cause, or by Mr. Collard for good reason, any stock options then held by Mr. Collard will also become immediately exercisable in full, and each outstanding restricted stock award will become fully vested and no longer subject to a right of repurchase by Cornerstone.
- (2) Reflects the fair value of the executive officer's unvested options at December 31, 2007.
- (3) The 2005 Equity Incentive Plan provides for accelerated vesting of option awards under specified circumstances following a change in control. For a more complete description of these circumstances, please see the section Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table beginning on page 265 of this proxy statement/prospectus.
- (4) Cornerstone is a private company and no public market exists for its common stock.
- (5) Mr. Esgro was not employed by Cornerstone on December 31, 2007.

### ***2007 Director Compensation***

In 2007, Cornerstone used cash compensation and option awards to attract and retain qualified candidates to serve on its board of directors. In setting director compensation, Cornerstone considered the significant amount of time directors expend in fulfilling their duties to the company as well as the skill level required. In connection with his service as a director in 2007, Mr. McEwan received \$60,000 in cash compensation and an option award of 500,000 shares of common stock.

The policy of the combined company with respect to the compensation of directors is expected to be determined at the first meeting of the board of directors following the consummation of the merger.

The table below summarizes the compensation paid by Cornerstone to its directors for the fiscal year ended December 31, 2007.

**DIRECTOR COMPENSATION**

<b>Name (1)</b>	<b>Fees Earned or Paid in Cash (\$)</b>	<b>Option Awards (\$)</b>	<b>Non-Equity Incentive Plan Compensation (\$)</b>	<b>All Other Compensation (\$)</b>	<b>Total (\$)</b>
Alastair McEwan	60,000	48,982(2)		42,813(3)	151,795

(1) Craig A. Collard, Cornerstone's President and Chief Executive Officer, is a director but receives no additional compensation for his services as a director. The compensation received by Mr. Collard as a Cornerstone employee is shown in the section Summary Compensation Table beginning on page 264 of this proxy statement/prospectus.

(2) The grant date fair value of this award was \$135,000. At December 31, 2007, the aggregate number of option awards held by Mr. McEwan was 1,500,000.

- (3) In addition to compensation for his service as a director, in 2007 Mr. McEwan received \$30,000 in cash compensation and \$12,813 in certain benefits for providing consulting services to Cornerstone. For a more complete description of Mr. McEwan's consulting arrangement, please see the section "Cornerstone Certain Relationships and Related Transactions, and Director Independence - Consulting Arrangement with Mr. McEwan" beginning on page 260 of this proxy statement/prospectus.

**Compensation Committee Interlocks and Insider Participation.**

The combined company's Compensation Committee of the board of directors will consist of Mr. Heffernan and Mr. Enright. Mr. Heffernan will be the chairman of the compensation committee. No member of the Compensation Committee will have been at any time an officer or employee of Cornerstone. None of the combined company's executive officers serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on the compensation committee of either Critical Therapeutics or Cornerstone. None of the combined company's executive officers serves, or in the past year has served, as a member of the compensation committee of any entity that has one or more executive officers serving on Cornerstone's board of directors.

## UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

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 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 balance sheet combines the historical consolidated balance sheets of Critical Therapeutics and Cornerstone as of March 31, 2008, giving effect to the combination as if it occurred on March 31, 2008, reflecting only pro forma adjustments expected to have a continuing impact on the combined results. 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 three months ended March 31, 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 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 or incorporated herein by reference. Please see the section entitled "Where You Can Find More Information" on page 297 of this proxy statement/prospectus for more information.



**UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET**  
**As of MARCH 31, 2008**

	<b>Historical(1)</b>				
	<b>Critical</b>		<b>Pro Forma</b>	<b>See</b>	<b>Pro Forma</b>
	<b>Therapeutics</b>	<b>Cornerstone</b>	<b>Adjustments</b>	<b>Note</b>	<b>Combined</b>
	<b>(Amounts in thousands)</b>				
<b>Assets</b>					
Current assets:					
Cash and cash equivalents	\$ 20,239	\$ 416	(1,726)	H	\$ 18,929
Accounts receivable, net	1,280	5,903			7,183
Inventory	9,666	3,855			13,521
Prepaid expenses and other current assets	1,839	1,109			2,948
Total current assets	33,024	11,283			42,581
Fixed assets, net	869	205	(71)	G	1,003
Intangible assets			10,000	B	
			(817)	G	9,183
Amounts due from related parties		38			38
Other assets	287	5,220	(24)	G	5,483
Total assets	\$ 34,180	\$ 16,746			\$ 58,288
<b>Liabilities</b>					
Current liabilities:					
Line of credit	\$	\$ 750			\$ 750
Current portion of:					
Accrued license fees	1,860	576			2,436
Deferred co-promotion fees	1,880		(1,880)	E	
Accounts payable	6,566	2,210			8,776
Accrued expenses	5,620	11,970	1,500	D	
			(1,726)	H	17,364
Income taxes payable		412			412
Total current liabilities	15,926	15,918			29,738
Long-term portion of:					
Accrued license fees, less current portion	1,775	2,959			4,734
Deferred co-promotion fees, less current portion	9,353		(9,353)	E	
Note payable, related party		9,412	(9,412)	H	
Commitments and contingencies					
Total liabilities	27,054	28,289			34,472
<b>Stockholders equity</b>					
Common stock	43	2	142	A	
			(43)	F	144

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Additional paid-in capital	209,247	885	26,797	A	
			(209,247)	F	
			9,412	H	37,112
Accumulated deficit	(202,151)	(12,430)	202,151	F	
			(1,100)	C	
			90	G	(13,440)
Accumulated other comprehensive loss	(13)		13	F	
Total stockholders equity (deficit)	7,126	(11,543)			23,816
Total liabilities and stockholders equity	\$ 34,180	\$ 16,746			\$ 58,288

(1) Amounts derived from the unaudited condensed consolidated financial statements of Critical Therapeutics beginning on page F-36 of this proxy statement/prospectus and from the unaudited consolidated financial statements of Cornerstone beginning on page F-85 of this proxy statement/prospectus.

**UNAUDITED PRO FORMA CONDENSED COMBINED  
STATEMENT OF OPERATIONS  
YEAR ENDED DECEMBER 31, 2007**

	<b>Historical(1)</b>				
	<b>Critical Therapeutics</b>	<b>Cornerstone</b>			
	(Amounts in thousands, except share and per share data)				
<b>Revenues</b>	\$ 12,869	\$ 28,071	\$		\$ 40,308
<b>Costs and expenses</b>					
Cost of products sold	4,233	6,709			10,942
Research and development	21,655	948			22,603
Sales, general and administrative	25,765	17,972	1,413	I	45,150
Total costs and expenses	51,653	25,629	1,413		78,695
Operating loss	(38,784)	2,442	(1,413)		(38,387)
Other income (expense)	1,811	(1,741)			70
Net income (loss) before income taxes	(36,973)	701	(1,413)		(38,317)
Provision for income taxes		130		J	130
Net income (loss)	\$ (36,973)	\$ 571	\$ (1,413)		\$ (38,447)
Net loss per share	\$ (0.87)				\$ (0.34)
Weighted-average common shares outstanding(2)	42,580,884	24,926,150	45,009,125	K	112,516,159

(1) Amounts derived from the audited consolidated financial statements of Critical Therapeutics beginning on page F-3 of this proxy statement/prospectus and from the audited consolidated financial statements of Cornerstone beginning on page F-53 of this proxy statement/prospectus.

(2) Common stock equivalents not considered in this calculation because they are antidilutive.

**UNAUDITED PRO FORMA CONDENSED COMBINED  
STATEMENT OF OPERATIONS  
THREE MONTHS ENDED MARCH 31, 2008**

	<b>Historical(1)</b>				
	<b>Critical Therapeutics</b>	<b>Cornerstone</b>			
	(Amounts in thousands, except share and per share data)				
<b>Revenues</b>	\$ 3,333	\$ 9,445	\$		\$ 12,195
<b>Costs and expenses</b>					
Cost of products sold	1,825	1,810			3,635
Research and development	5,364	98			5,462
Sales, general and administrative	7,092	6,171	353	I	13,616
Total costs and expenses	14,281	8,079	353		22,713
Operating income (loss)	(10,948)	1,366	(353)		(10,518)
Other income (expense)	169	(378)			(209)
Net income (loss) before income taxes	(10,779)	988	(353)		(10,727)
Provision for income taxes		319		J	319
Net income (loss)	\$ (10,779)	\$ 669	\$ (353)		\$ (11,046)
Net loss per share	\$ (0.25)				\$ (0.08)
Weighted-average common shares outstanding(2)	42,805,348	40,368,925	61,081,087	K	144,255,360

- (1) Amounts derived from the unaudited consolidated financial statements of Critical Therapeutics beginning on page F-36 of this proxy statement/prospectus and from the unaudited consolidated financial statements of Cornerstone beginning on page F-85 of this proxy statement/prospectus.
- (2) Common stock equivalents only considered in the computation of Cornerstone's weighted-average common shares outstanding as Critical Therapeutics and pro forma combined common stock equivalents are antidilutive.

**NOTES TO UNAUDITED PRO FORMA CONDENSED  
COMBINED FINANCIAL STATEMENTS**

**(1) Description of Transaction and Basis of Presentation**

On May 1, 2008, Critical Therapeutics, Cornerstone and a wholly owned subsidiary of Critical Therapeutics, Neptune Acquisition Corp., entered into a merger agreement, which provides that Neptune Acquisition Corp. will merge with and into Cornerstone. This transaction will be accounted for under the purchase method of accounting. Under the purchase method of accounting, the assets and liabilities of Critical Therapeutics will be recorded as of the acquisition date, at their respective fair values, and consolidated with those of Cornerstone. The reported consolidated financial condition and results of operations after completion of the merger will reflect these fair values. The purchase price, including the acquiring company's merger related fees, is expected to be approximately \$28,457,000.

Under the terms of the merger agreement, each share of Cornerstone 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. Each restricted stock unit and outstanding option, 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. All stock option plans or other stock or equity-related plans of Cornerstone and warrants to purchase Cornerstone's common stock shall be assumed by Critical Therapeutics on the same terms and conditions as were applicable under Cornerstone immediately prior to the effective time of merger. Cornerstone stockholders will not receive any fractional shares of Critical Therapeutics' common stock in the merger. Instead, any stockholder who would otherwise be entitled to a fractional share of Critical Therapeutics' common stock will be entitled to receive an amount of cash, without interest, equal to the product of such fraction multiplied by the average last reported sales price for Critical Therapeutics' common stock during the ten trading days preceding the effective time of the merger.

The unaudited pro forma condensed combined balance sheets and condensed combined statements of operations for all periods presented assume that the convertible promissory note of Cornerstone issued in April 2004, amended in June 2006, and outstanding at March 31, 2008, had been converted into 6,491,034 shares of Cornerstone common stock at March 31, 2008.

The transaction is expected to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code.

The merger is subject to customary closing conditions, including the approval of the merger by Critical Therapeutics and Cornerstone's stockholders and regulatory approvals.

**(2) Purchase Price**

A preliminary estimate of the purchase price is as follows (table in thousands):

Estimated fair value of Critical Therapeutics shares outstanding	\$ 26,957
Estimated acquiring company transaction costs incurred	1,500

Estimated purchase price

\$ 28,457

For pro forma purposes, the fair value of Critical Therapeutics common stock used in determining the purchase price was \$0.62 per share, which was the closing price on April 30, 2008. The per share value of common stock of Critical Therapeutics on the opening of trading on the day following the consummation of the merger will be used to determine the actual consideration paid in accordance with FASB No. 141.

**NOTES TO UNAUDITED PRO FORMA CONDENSED  
COMBINED FINANCIAL STATEMENTS (Continued)**

For purposes of this pro forma analysis, the estimated purchase price has been allocated based on a preliminary estimate of the fair value of the assets acquired and liabilities assumed as of March 31, 2008 (table in thousands):

Cash and cash equivalents	\$ 20,239
Accounts receivable	1,280
Inventory	9,666
Prepaid expenses and other current assets	1,839
Fixed assets	798
Other assets	263
Intangible assets:	
Product rights	9,183
Acquired in-process research and development	1,010
Assumed liabilities	(15,821)
 Total	 \$ 28,457

The purchase price allocation will remain preliminary until Cornerstone completes a final valuation of the assets acquired and liabilities assumed as of the date that the merger is consummated. The final amounts allocated to assets and liabilities acquired could differ significantly from the amounts presented in the unaudited pro forma condensed combined financial statements.

The amount allocated to acquired identifiable intangible assets has been attributed to the following categories (table in thousands):

ZYFLO CR Product Rights	\$ 9,183
alpha-7 program	1,010
 Total	 \$ 10,193

The estimated fair value attributed to the ZYFLO CR Product Rights was determined based on a discounted forecast of the estimated net future cash flows to be generated from the ZYFLO CR Product Rights. The estimated fair value attributed to the ZYFLO CR Product Rights is estimated to have a 6.5 year useful life from the expected closing date of the merger.

The amount allocated to in-process research and development for the alpha-7 program represents an estimate of the fair value of purchased in-process technology for this research program that, as of the expected closing date of the merger, will not have reached technological feasibility and have no alternative future use. The alpha-7 program is the only Critical Therapeutics research program that had advanced to a stage of development where management believed reasonable net future cash flow forecasts could be prepared and a reasonable likelihood of technical success existed.

The estimated fair value of the alpha-7 program was determined based on a discounted forecast of the estimated net future royalties from the anticipated out-licensing of the alpha-7 program considering the estimated probability of technical success and FDA approval. In-process research and development will be expensed immediately following consummation of the merger.

**(3) Pro Forma Adjustments**

- A. To record the fair value of Critical Therapeutics outstanding common stock assumed in connection with the merger. Cash paid in lieu of fractional shares will be from existing cash balances which has not been reflected.



**NOTES TO UNAUDITED PRO FORMA CONDENSED  
COMBINED FINANCIAL STATEMENTS (Continued)**

- B. To record the estimated fair value of acquired identifiable intangible asset (ZYFLO CR Product Rights) arising from the merger.
- C. To record the estimated fair value of in-process research and development acquired in the merger. Because this expense is directly attributable to the acquisition and will not have a continuing impact, it is not reflected in the pro forma condensed combined statements of operations. However, this item will be recorded as an expense immediately following consummation of the merger.
- D. To record estimated Cornerstone transaction costs of \$1,500,000; transaction costs incurred by Critical Therapeutics will be expensed as incurred. These amounts are not reflected in the pro forma statement of operations.
- E. To eliminate deferred co-promotion fees for ZYFLO CR as Critical Therapeutics has no future performance obligations or continuing obligations to incur any significant costs in connection with this agreement.
- F. To eliminate and adjust the historical equity accounts of Critical Therapeutics.
- G. To reflect the pro rata reduction of amounts allocated to non-financial and non-current assets acquired due to the excess fair value of acquired assets over the estimated purchase price as follows (table in thousands):

Acquired identifiable intangible assets (ZYFLO CR Product Rights )	\$ 817
In-process research and development (alpha-7 program)	90
Fixed assets	71
Other assets	24
 Total	 \$ 1,002

- H. To reflect the issuance of common stock and payment in cash of interest due in settlement of the convertible promissory note.
- I. To record the amortization of the excess purchase price allocated to intangible assets (ZYFLO CR Product Rights) of \$9,183,000 over an estimated life of 6.5 years.
- J. The tax effect of the pro forma adjustments was calculated at the statutory rate and was determined to be zero because of the availability of net operating loss (NOL) and R&D credit carryforwards. Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as well as similar state provisions. It is expected that the combined company will continue to provide a full valuation allowance on its deferred tax assets.

**NOTES TO UNAUDITED PRO FORMA CONDENSED  
COMBINED FINANCIAL STATEMENTS (Continued)**

K. To reflect the weighted average shares outstanding as follows:

	<b>As of December 31, 2007</b>			
	<b>Critical Therapeutics</b>	<b>Cornerstone</b>	<b>Pro Forma Adjustments</b>	<b>Total</b>
Weighted average basic and diluted shares:				
Preliminary shares outstanding	42,580,884	24,926,150		67,507,034
Number of shares common stock issued:				
Exchange ratio		2.805699		
Shares issued to Cornerstone stockholders, net		69,935,275		69,935,275
Pro forma adjustment	69,935,275	(69,935,275)	(24,926,150)	(24,926,150)
Total shares outstanding, post exchange	112,516,159			112,516,159

	<b>As of March 31, 2008</b>			
	<b>Critical Therapeutics</b>	<b>Cornerstone</b>	<b>Pro Forma Adjustments</b>	<b>Total</b>
Weighted average basic and diluted shares:				
Preliminary shares outstanding	42,805,348	33,877,891		78,962,348
Conversion of note payable, related party		6,491,034		6,491,034
Number of shares common stock issued:	42,805,348	(40,368,925)		85,453,382
Exchange ratio		2.513072		
Shares issued to Cornerstone stockholders, net		101,450,012		101,450,012
Pro forma adjustment	101,450,012	(101,450,012)	(40,368,925)	(40,368,925)
Total shares outstanding, post exchange	144,255,360			144,255,360

## DESCRIPTION OF CRITICAL THERAPEUTICS CAPITAL STOCK

The following description of Critical Therapeutics capital stock summarizes the material terms and provisions of the capital stock. For the complete terms of Critical Therapeutics capital stock, please refer to Critical Therapeutics certificate of incorporation and bylaws. The terms of Critical Therapeutics capital stock may also be affected by Delaware law.

### **Authorized Capital Stock**

Critical Therapeutics authorized capital stock consists of 90,000,000 shares of common stock, \$0.001 par value per share, and 5,000,000 shares of preferred stock, \$0.001 par value per share. As of June 30, 2008, there were 43,370,448 shares of common stock outstanding and no shares of preferred stock outstanding. Upon the consummation of the merger, there will be approximately 125.7 million shares of Critical Therapeutics common stock outstanding and approximately 101.5 million shares of Critical Therapeutics common stock will be issued to Cornerstone's common stockholders in connection with the merger. 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 stock options, will be assumed by Critical Therapeutics and will become an option to acquire, on the same terms and conditions as were applicable under such Cornerstone stock option immediately prior to the effective time of the merger, shares of Critical Therapeutics common stock. Each warrant to purchase shares of Cornerstone common stock outstanding immediately prior to the effective time of the merger shall be assumed by Critical Therapeutics and will become a warrant to acquire, on the same terms and conditions as were applicable under such warrant, shares of Critical Therapeutics common stock.

### **Common Stock**

#### *Voting*

For all matters submitted to a vote of stockholders, each holder of common stock is entitled to one vote for each share registered in the stockholder's name. Critical Therapeutics common stock does not have cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. An election of directors by Critical Therapeutics stockholders is determined by a plurality of the votes cast by the stockholders entitled to vote in the election.

#### *Dividends*

Holders of common stock are entitled to share ratably in any dividends declared by Critical Therapeutics board of directors, subject to any preferential dividend rights of any outstanding preferred stock. Dividends consisting of shares of common stock may be paid to holders of shares of common stock. Critical Therapeutics has never declared or paid cash dividends on Critical Therapeutics capital stock. Critical Therapeutics does not intend to pay cash dividends in the foreseeable future.

#### *Liquidation and Dissolution*

If Critical Therapeutics is liquidated or dissolved, the holders of its common stock will be entitled to share ratably in all the assets that remain after Critical Therapeutics pays its liabilities, subject to the prior rights of any outstanding preferred stock.

***Other Rights and Restrictions***

Holders of Critical Therapeutics common stock do not have preemptive rights, and they have no right to convert their common stock into any other securities. Critical Therapeutics common stock is not subject to redemption. Critical Therapeutics certificate of incorporation and bylaws do not restrict the ability of a holder of common stock to transfer the stockholder's shares of common stock. When Critical Therapeutics issues

shares of common stock under this prospectus, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

### ***Listing***

Critical Therapeutics' common stock is listed on The NASDAQ Capital Market under the symbol CRTX. On June 30, 2008, the last reported sale price for Critical Therapeutics' common stock on The NASDAQ Capital Market was \$0.37 per share. As of June 30, 2008 Critical Therapeutics had approximately 77 stockholders of record.

### ***Transfer Agent and Registrar***

The transfer agent and registrar for Critical Therapeutics' common stock is Mellon Investor Services LLC.

### **Preferred Stock**

Critical Therapeutics' board of directors is authorized, subject to any limitations under its certificate of incorporation or prescribed by law, without further stockholder approval, to issue up to an aggregate of 5,000,000 shares of preferred stock. Critical Therapeutics' board of directors may establish the applicable and relative designations, number of authorized shares, dividend rates and terms, redemption or sinking fund provisions, conversion or exchange rates, anti-dilution provisions, voting rights, liquidation preferences and other terms, preferences and limitations of any series of preferred stock it determines to issue.

### **Delaware Law and Certificate of Incorporation and Bylaw Provisions**

#### ***Anti-Takeover Provisions***

Critical Therapeutics is subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a business combination with any interested stockholder for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of Critical Therapeutics' board of directors or unless the business combination is approved in a prescribed manner. A business combination includes, among other things, a merger or consolidation involving Critical Therapeutics and the interested stockholder and the sale of more than 10% of Critical Therapeutics' assets. In general, an interested stockholder is any entity or person beneficially owning 15% or more of Critical Therapeutics' outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. The restrictions contained in Section 203 of the Delaware General Corporation Law are not applicable to any of Critical Therapeutics' existing stockholders.

#### ***Staggered Board***

Critical Therapeutics' certificate of incorporation and its bylaws divide its board of directors into three classes with staggered three-year terms. In addition, Critical Therapeutics' certificate of incorporation and its bylaws provide that directors may be removed only for cause and only by the affirmative vote of the holders of 75% of Critical Therapeutics' shares of capital stock present in person or by proxy and entitled to vote. Under Critical Therapeutics' certificate of incorporation, any vacancy on Critical Therapeutics' board of directors, including a vacancy resulting from an enlargement of its board of directors, may be filled only by vote of a majority of Critical Therapeutics' directors then in office. The classification of Critical Therapeutics' board of directors and the limitations on the removal of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of Critical Therapeutics.



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

Critical Therapeutics' certificate of incorporation and its bylaws provide that any action required or permitted to be taken by its stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before the meeting and may not be taken by written action in lieu of a meeting. Critical Therapeutics' certificate of incorporation also provides that, except as otherwise required by law, a special meeting of the stockholders can only be called by Critical Therapeutics' chairman of the board, Critical Therapeutics' chief executive officer or Critical Therapeutics' board of directors. Critical Therapeutics' bylaws provide that, except as otherwise required by law, a special meeting of the stockholders can only be called by Critical Therapeutics' chairman of the board, Critical Therapeutics' chief executive officer, Critical Therapeutics' board of directors or Critical Therapeutics' president (if the president is a different individual than the chief executive officer). In addition, Critical Therapeutics' bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to Critical Therapeutics' secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of Critical Therapeutics' outstanding voting securities.

***Super-Majority Voting***

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Critical Therapeutics' bylaws may be amended or repealed by a majority vote of its board of directors or the affirmative vote of the holders of at least 75% of the votes which all its stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes which all Critical Therapeutics' stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of Critical Therapeutics' certificate of incorporation described in the prior two paragraphs.

***Limitation of Liability and Indemnification of Officers and Directors***

Critical Therapeutics' certificate of incorporation contains provisions permitted under the Delaware General Corporation Law relating to the liability of directors. The provisions eliminate a director's liability for monetary damages for a breach of fiduciary duty, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty. Further, Critical Therapeutics' certificate of incorporation contains provisions to indemnify Critical Therapeutics' directors and officers to the fullest extent permitted by the Delaware General Corporation Law.

**COMPARISON OF RIGHTS OF HOLDERS OF CRITICAL THERAPEUTICS STOCK AND  
CORNERSTONE S COMMON STOCK**

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, as amended, including as described in Proposal 2 and Proposal 3 to the extent applicable, and the bylaws of Critical Therapeutics.

The following is a summary of the material differences between the rights of Critical Therapeutics' stockholders and the rights of Cornerstone's stockholders under each company's respective certificate of incorporation and bylaws. While Critical Therapeutics believes that this summary covers the material differences between the two, this summary may not contain all of the information that is important to you. This summary is not intended to be a complete discussion of the respective rights of Critical Therapeutics' and Cornerstone's stockholders and is qualified in its entirety by reference to the Delaware General Corporation Law and the various documents of Critical Therapeutics and Cornerstone that are referred to in this summary. You should carefully read this entire proxy statement/prospectus and the other documents referred to in this proxy statement/prospectus for a more complete understanding of the differences between being a stockholder of Critical Therapeutics and being a stockholder of Cornerstone. Critical Therapeutics has filed copies of its certificate of incorporation and bylaws with the SEC, which are exhibits to the registration statement of which this proxy statement/prospectus is a part, and will send copies of these documents to you upon your request.

	<b>Critical Therapeutics</b>	<b>Cornerstone</b>
<b>Authorized Capital Stock</b>	Critical Therapeutics' amended and restated certificate of incorporation authorizes the issuance of up to 90,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share.	Cornerstone's amended certificate of incorporation authorizes the issuance of up to 50,000,000 shares of common stock, par value \$0.0001 per share.
<b>Number of Directors</b>	Critical Therapeutics' amended and restated bylaws provide that the number of directors be established by the board of directors, subject to the rights of holders of any series of preferred stock to elect directors. Critical Therapeutics' board of directors currently consists of four directors.	Cornerstone's amended and restated bylaws provide that the number of directors shall be determined from time to time by resolution of the stockholders or the board of directors, but in no event shall be less than one. Cornerstone's board of directors currently consists of two directors.
<b>Stockholder Nominations</b>	Critical Therapeutics' amended and restated bylaws provide that in order for a stockholder to make a director nomination or propose business at an annual meeting of the stockholders, the stockholder must give timely written notice to Critical	Cornerstone's amended certificate of incorporation and amended and restated bylaws do not contain provisions relating to stockholder nominations and proposals.



Therapeutics Secretary not less than the 90<sup>th</sup> day nor later than the 120<sup>th</sup> day prior to the first anniversary of the preceding year's annual meeting (with certain adjustments if the date of the annual meeting is advanced by more than 20 days or delayed by more than 60 days from the first anniversary of the preceding year's annual meeting, and in order for a stockholder to make a director nomination at a special meeting

**Critical Therapeutics**

**Cornerstone**

of the stockholders, the stockholder must give timely written notice to Critical Therapeutics Secretary not less than the 120<sup>th</sup> day prior to such special meeting nor later than the close of business on the later of (i) the 90<sup>th</sup> day prior to such special meeting and (ii) the 10<sup>th</sup> day following the day on which the notice of the date of such special meeting was mailed or public disclosure of such special meeting was made.

**Classification of Directors**

Critical Therapeutics amended and restated certificate of incorporation and amended and restated bylaws provide that the board of directors is divided into three classes: Class I, Class II and Class III. Each director serves for a term ending on the date of the third annual meeting following the annual meeting at which such director was elected.

Cornerstone's board of directors is not divided into classes.

**Removal of Directors**

Under Critical Therapeutics amended and restated certificate of incorporation and amended and restated bylaws, a director may be removed from office only with cause by the affirmative vote of the holders of 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors, subject to the rights of holders of any series of preferred stock.

Under Cornerstone's amended and restated bylaws, a director may be removed from office with or without cause by a vote of the holders of a majority of the outstanding shares entitled to vote at an election of directors.

**Filling Vacancies on the Board of Directors**

Critical Therapeutics amended and restated certificate of incorporation and amended and restated bylaws provide that any vacancy or newly created directorships in the board of directors shall be filled only by vote of a majority of the directors in office, although less than a quorum, or by a sole remaining director and shall not be filled by the stockholders, subject to the rights of holders of any series of preferred stock. A director elected to fill a vacancy shall hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of a successor and to such

Cornerstone's amended and restated bylaws provide that any vacancy or newly created directorships in the board of directors may be filled by vote of a majority of the directors in office, or, if the directors remaining in office constitute less than a quorum, by the affirmative vote of a majority of all remaining directors, or by the sole remaining director. If the vacant office was held by a director elected by a voting group, only the remaining director or directors elected by that voting group or the holders of shares of that voting group are entitled to fill the vacancy. A director elected to fill a vacancy shall be elected for the unexpired

director's earlier death, resignation or removal.

term of such director's predecessor in office. The stockholders may elect a director at any time to fill any vacancy not filled by the directors.

**Stockholder Action by  
Written Consent**

Critical Therapeutics' amended and restated certificate of incorporation and amended and restated bylaws specify

Cornerstone's amended and restated bylaws permit any action which is required or permitted to be taken at a

286

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### **Critical Therapeutics**

that no action shall be taken by the stockholders by written consent in lieu of a meeting.

### **Cornerstone**

meeting of the stockholders to be taken without a meeting, without prior notice and without a vote, if a consent in writing, setting forth the action so taken, is signed and dated by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted. Stockholders may act by written consent to elect directors; provided, however, that, if such consent is less than unanimous, such action by written consent may be in lieu of holding an annual meeting only if all of the directorships to which directors could be elected at an annual meeting held at the effective time of such action are vacant and are filled by such action.

#### **Notice of Annual Meeting**

Under Critical Therapeutics' amended and restated bylaws, written notice of the annual meeting must include the date, time and place of such meeting and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting. Notice shall be given not less than 10 nor more than 60 days prior to the annual meeting to each stockholder entitled to vote at such meeting.

Under Cornerstone's amended and restated bylaws, written notice of the annual meeting must include the time and place of such meeting and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting. Notice shall be given not less than 10 nor more than 60 days prior to the annual meeting to each stockholder of record entitled to vote at such meeting.

#### **Special Meeting of Stockholders**

Critical Therapeutics' amended and restated certificate of incorporation provides that a special meeting of stockholders may be called by the board of directors, the chairman of the board or the chief executive officer, but such special meetings may not be called by any other person or persons. Critical Therapeutics' amended and restated bylaws provides that a special meeting of stockholders may be called by the board of directors, the chairman of the board, the chief executive officer or the president (if the president shall be a different individual than the chief executive

Cornerstone's amended and restated bylaws provide that special meetings of the stockholders may be called at any time by the President, the Secretary, or the board of directors of Cornerstone, but such special meetings may not be called by any other person or persons.

officer), but such special meetings may not be called by any other person or persons. Stockholders are not entitled to call special meetings of stockholders unless permitted under the Delaware General Corporation Law. Written notice of special meetings must

**Critical Therapeutics**

**Cornerstone**

include the date, time, place and purpose of such meeting and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting. Notice shall be given not less than 10 nor more than 60 days prior to the special meeting to each stockholder entitled to vote at such meeting.

**Amendment of Certificate of Incorporation**

Critical Therapeutics' amended and restated certificate of incorporation provides that Critical Therapeutics reserves the right to amend, alter, change or repeal any provision of the certificate of incorporation.

Cornerstone's amended certificate of incorporation provides that Cornerstone reserves the right to amend or repeal any provision of the certificate of incorporation.

**Amendment of Bylaws**

Critical Therapeutics' amended and restated certificate of incorporation provides that the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors may adopt, amend, alter or repeal the bylaws, and the board of directors also has the power to adopt, amend, alter or repeal the bylaws by an affirmative vote of a majority of the directors present at any regular or special meeting of the board of directors at which a quorum is present, subject to the terms of any series of preferred stock.

Cornerstone's amended certificate of incorporation provides that the board of directors is authorized to adopt, amend or repeal the bylaws. Cornerstone's amended and restated bylaws provide that the bylaws may be amended or repealed and new bylaws may be adopted by the affirmative vote of the holders of a majority of the voting power of Cornerstone, or by the affirmative vote of a majority of the directors then holding office at any regular or special meeting of the board of directors or by unanimous written consent.

**Voting Stock**

Under Critical Therapeutics' amended and restated certificate of incorporation, the holders of common stock are entitled to vote at all meetings of the stockholders and shall be entitled to one vote for each share of stock held by them respectively; provided however, that the holders of common stock are not entitled to vote on any amendment to the certificate of incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected stock are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon. The voting rights of the

Under Cornerstone's amended and restated bylaws, each stockholder is entitled to one vote for each share of capital stock of Cornerstone held by such stockholder on each matter submitted to a vote at a meeting of stockholders.

holders of common stock are subject to and qualified by the rights of the holders of preferred stock of any series as may be designated by the board of directors upon any issuance of preferred stock of any series.

**Critical Therapeutics**

**Cornerstone**

**Conversion Rights and Protective Provisions**

Under Critical Therapeutics' amended and restated certificate of incorporation, holders of Critical Therapeutics stock have no preemptive or other rights.

Under Cornerstone's amended certificate of incorporation, holders of Cornerstone stock have no preemptive rights, conversion rights, protective provisions, nor any other rights.

**Dividends**

Critical Therapeutics' amended and restated certificate of incorporation provides that dividends may be declared and paid on the common stock from funds lawfully available therefor as and when determined by the board of directors and subject to any preferential dividend or other rights of any then outstanding preferred stock.

Cornerstone's amended and restated bylaws provide that the board of directors may from time to time declare, and Cornerstone may pay, dividends on outstanding shares.

**Indemnification and Limitation of Liability**

Critical Therapeutics' amended and restated certificate of incorporation provides that directors are not personally liable to Critical Therapeutics or its stockholders for monetary damages for any breach of fiduciary duty as a director, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty. Critical Therapeutics' amended and restated certificate of incorporation provides that Critical Therapeutics shall indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was, or has agreed to become, a director or officer of Critical Therapeutics, or is or was serving, or has agreed to serve, at the request of Critical Therapeutics, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by or on behalf of such person in connection with such action, suit or

Cornerstone's amended certificate of incorporation provides that directors are not personally liable to Cornerstone or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent that the elimination or limitation of liability is not permitted under the Delaware General Corporation Law. Cornerstone's amended and restated bylaws provide that any person who at any time serves or has served (i) as a director, officer, employee or agent of Cornerstone, (ii) at the request of Cornerstone as a director, officer, partner, trustee, employee or agent of another foreign or domestic corporation, partnership, joint venture, trust, or other enterprise, or (iii) at the request of Cornerstone as a trustee or administrator under an employee benefit plan, or is called as a witness at a time when he or she has not been made a named defendant or respondent to any proceeding, shall have a right to be indemnified by Cornerstone to the fullest extent from time to time permitted by law against liability and expenses in any proceeding (including without limitation a proceeding brought by or on behalf of Cornerstone itself), arising out of his or her status as such or activities in any of the foregoing capacities.



proceeding and any appeal therefrom.

289

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**PRINCIPAL STOCKHOLDERS OF CRITICAL THERAPEUTICS**

The following table sets forth information regarding beneficial ownership of Critical Therapeutics common stock as of June 30, 2008 by:

each person, entity or group of affiliated persons or entities known to Critical Therapeutics to be the beneficial owner of more than 5% of the outstanding shares of Critical Therapeutics common stock;

each member of Critical Therapeutics board of directors;

Critical Therapeutics President and Chief Executive Officer, Chief Financial Officer and two other executive officers who were serving as executive officers on December 31, 2007, Critical Therapeutics former President and Chief Executive Officer and one additional former executive officer who would have been among its most highly compensated executive officers if he had been serving as an executive officer on December 31, 2007; and

all of Critical Therapeutics directors and executive officers as a group.

Beneficial ownership is determined in accordance with the applicable rules of the SEC and includes voting or investment power with respect to shares of Critical Therapeutics common stock. Shares of common stock issuable under stock options and warrants that are currently exercisable or exercisable within 60 days of June 30, 2008 are deemed to be beneficially owned by the person holding the option or warrant for purposes of calculating the percentage ownership of that person but are not deemed outstanding for purposes of calculating the percentage ownership of any other person. The information set forth below is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares deemed beneficially owned in this table does not constitute an admission of beneficial ownership of those shares. Unless otherwise indicated, to Critical Therapeutics knowledge, all persons named in the table have sole voting and investment power with respect to the shares of common stock beneficially owned by them, except, where applicable, to the extent authority is shared by spouses under community property laws.

Name and Address of Beneficial Owner(1)	Number of	Shares	Shares	Total	Percentage
	Outstanding	Underlying	Underlying		
	Shares	Warrants	Options	Shares	Common
	Beneficially	Currently	Exercisable	Beneficially	Stock
	Owned	Exercisable(2)	within 60	Owned	Beneficially
			Days		Owned
<b>5% Stockholders</b>					
Funds managed by Healthcare Ventures(3) 44 Nassau Street, Second Floor Princeton, NJ 08542	5,153,323	383,212		5,536,535	12.7%
Funds managed by Advanced Technology Ventures(4)	3,182,132	447,081		3,629,213	8.3%

Bay Colony Corporate Center  
1000 Winter Street, Suite 3700  
Waltham, MA 02541

MedImmune Ventures, Inc. One MedImmune Way Gaithersburg, MD 20878	2,663,642		2,663,642	6.1%
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***Directors and Named Executive Officers***

Trevor Phillips, Ph.D.(5) <i>President and Chief Executive Officer and Director</i>	85,824	542,800	628,624	1.4%
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Christopher Mirabelli, Ph.D.(6) <i>Director</i>	5,153,323	383,212	5,536,535	12.7%
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Jean George(7) <i>Director</i>	3,182,132	447,081	32,916	3,662,129	8.4%
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Richard W. Dugan <i>Director</i>		57,916	57,916	*
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Name and Address of Beneficial Owner(1)	Number of	Shares	Shares	Total	Percentage
	Outstanding	Underlying	Underlying		
	Shares	Warrants	Options	Shares	Common
	Beneficially	Currently	Exercisable	Beneficially	Stock
	Owned	Exercisable(2)	within 60	Owned	Beneficially
			Days		Owned
Thomas P. Kelly(8) <i>Chief Financial Officer and Senior Vice President of Finance and Corporate Development</i>	90,700		37,500	128,200	*
Scott B. Townsend, Esq.(9) <i>Senior Vice President of Legal Affairs, General Counsel and Secretary</i>	94,868		160,767	255,635	*
Jeffrey E. Young(10) <i>Vice President of Finance, Chief Accounting Officer and Treasurer</i>	52,469		84,683	137,152	*
Frank E. Thomas(11) <i>Former President and Chief Executive Officer</i>	52,033		667,029	719,062	1.6%
Dana Hilt, M.D.(12) <i>Former Chief Medical Officer and Senior Vice President of Clinical Development</i>					*
All executive officers and directors as a group (7 persons, consisting of 4 officers and 3 non-employee directors)	8,659,316	830,293	916,582	10,406,191	23.0%

\* Represents beneficial ownership of less than one percent of common stock.

- (1) Unless otherwise indicated, the address of each beneficial owner is care of Critical Therapeutics, Inc., 60 Westview Street, Lexington, MA 02421.
- (2) Consists of shares underlying warrants to purchase common stock at \$6.58 per share issued in connection with a private placement of common stock and warrants in June 2005.
- (3) Consists of 4,058,432 shares of common stock held by HealthCare Ventures VI, L.P. and 1,094,891 shares of common stock and warrants to purchase 383,212 shares of common stock held by HealthCare Ventures VII, L.P. Christopher Mirabelli, a member of the board of directors, is a General Partner of HealthCare Partners VI, L.P., the general partner of HealthCare Ventures VI, L.P., and a General Partner of HealthCare Partners VII, L.P., the general partner of HealthCare Ventures VII, L.P. Dr. Mirabelli disclaims beneficial ownership of the shares held by the funds managed by HealthCare Ventures, except to the extent of his pecuniary interest therein.
- (4) Consists of 2,554,802 shares of common stock and warrants to purchase 359,696 shares of common stock held by Advanced Technology Ventures VII, L.P.; 102,522 shares of common stock and warrants to purchase

14,434 shares of common stock held by Advanced Technology Ventures VII (B), L.P.; 49,279 shares of common stock and warrants to purchase 6,938 shares of common stock held by Advanced Technology Ventures VII (C), L.P.; 15,225 shares of common stock and warrants to purchase 2,144 shares of common stock held by ATV Entrepreneurs VII, L.P.; 5,714 shares of common stock held by ATV Alliance 2003, L.P.; 427,315 shares of common stock and warrants to purchase 60,037 shares of common stock held by Advanced Technology Ventures VI, L.P.; and 27,275 shares of common stock and warrants to purchase 3,832 shares of common stock held by ATV Entrepreneurs VI, L.P. Jean George, a member of the board of directors, is a Managing Director of the general partner of certain of the funds managed by Advanced Technology Ventures. Ms. George disclaims beneficial ownership of the shares held by the funds managed by Advanced Technology Ventures, except to the extent of her pecuniary interest therein.

- (5) Includes 17,500 shares of restricted stock issued to Dr. Phillips in December 2006 that will vest in December 2008 and 25,000 shares of restricted stock issued to Dr. Phillips in November 2007 that will vest in November 2009. In addition, includes 3,200 shares of common stock held by Dr. Phillips children. Dr. Phillips disclaims beneficial ownership of the foregoing 3,200 shares held by his children except to the extent of his pecuniary interest therein. Dr. Phillips was elected as a director effective March 4, 2008 and appointed as President and Chief Executive Officer effective April 1, 2008.
- (6) Consists of 5,153,323 shares of common stock and warrants to purchase 383,212 shares of common stock held by funds managed by HealthCare Ventures. Dr. Mirabelli is a general partner of HealthCare Partners VI, L.P., the general partner of HealthCare Ventures VI, L.P., and a General Partner of HealthCare Partners VII, L.P., the general partner of HealthCare Ventures VII, L.P. Dr. Mirabelli disclaims beneficial ownership of the shares held by the funds managed by HealthCare Ventures, except to the extent of his pecuniary interest therein.
- (7) Includes 3,182,132 shares of common stock and warrants to purchase 447,081 shares of common stock held by funds managed by Advanced Technology Ventures. Ms. George is a Managing Director of the general partner of certain of the funds managed by Advanced Technology Ventures. Ms. George disclaims beneficial ownership of the shares held by the funds managed by Advanced Technology Ventures, except to the extent of her pecuniary interest therein.
- (8) Includes (i) 26,700 shares of restricted stock issued to Mr. Kelly in August 2007 that will vest in equal installments in August 2008 and August 2009, (ii) 12,500 shares of restricted stock issued to Mr. Kelly in November 2007 that will vest in November 2009 and (iii) 35,000 shares of restricted stock issued to Mr. Kelly in February 2008 that will vest in equal installments in August 2008 and February 2010.
- (9) Includes (i) 13,350 shares of restricted stock issued to Mr. Townsend in December 2006 that will vest in December 2008, (ii) 12,500 shares of restricted stock issued to Mr. Townsend in November 2007 that will vest in November 2009 and (iii) 35,000 shares of restricted stock issued to Mr. Townsend in February 2008 that will vest in equal installments in August 2008 and February 2010.
- (10) Includes 13,350 shares of restricted stock issued to Mr. Young in December 2006 that will vest in December 2008 and 12,500 shares of restricted stock issued to Mr. Young in November 2007 that will vest in November 2009.
- (11) Mr. Thomas resigned as a director effective March 2, 2008 and as President and Chief Executive Officer effective March 31, 2008.
- (12) Dr. Hilt resigned as Chief Medical Officer and Senior Vice President of Clinical Development effective September 25, 2007.

**PRINCIPAL STOCKHOLDERS OF CORNERSTONE**

The following table sets forth information regarding beneficial ownership of Cornerstone's common stock as of June 30, 2008 by:

each person, entity or group of affiliated persons or entities known to Cornerstone to be the beneficial owner of more than 5% of the outstanding shares of Cornerstone's common stock;

each of member of Cornerstone's board of directors;

Cornerstones (i) President and Chief Executive Officer, (ii) Vice President Sales and Marketing, (iii) Chief Medical Officer, (iv) Executive Vice President Commercial Operations and (v) Vice President, Finance; and

all of Cornerstone's directors and executive officers as a group.

Beneficial ownership is determined in accordance with the applicable rules of the SEC and includes voting or investment power with respect to shares of Cornerstone's common stock. Shares of common stock issuable under stock options and warrants that are currently exercisable or exercisable within 60 days of June 30, 2008 are deemed to be beneficially owned by the person holding the option or warrant for purposes of calculating the percentage ownership of that person but are not deemed outstanding for purposes of calculating the percentage ownership of any other person. The information set forth below is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares deemed beneficially owned in this table does not constitute an admission of beneficial ownership of those shares. Unless otherwise indicated, to Cornerstone's knowledge, all persons named in the table have sole voting and investment power with respect to the shares of common stock beneficially owned by them, except, where applicable, to the extent authority is shared by spouses under community property laws.

Name and Address of Beneficial Owner(1)	Number of	Shares	Shares	Total Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned
	Outstanding	Underlying	Underlying		
	Shares Beneficially Owned	Warrants Currently Exercisable(2)	Options Exercisable within 60 Days		
<b>5% Stockholders</b>					
Craig A. Collard(3) <i>President and Chief Executive Officer and Director</i> Cornerstone Biopharma Holdings, Ltd.	13,450,000		300,000	13,750,000	54.5%
Steven M. Lutz(4) <i>Executive Vice President, Commercial Operations</i> Lutz Family Limited Partnership	13,450,000			13,450,000	54.0%
James V. Baker(5)	2,845,000		281,250	3,126,250	12.4%
	2,845,000			2,845,000	11.4%
	3,100,000		50,000	3,150,000	12.6%

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ProPharm Investments, LLC		1,311,903	1,311,903	5.0%
<b><i>Other Directors and Named Executive Officers</i></b>				
Chenyqua Baldwin(6) <i>Vice President, Finance</i>	750,000	242,500	992,500	3.9%
Brian Dickson, M.D.(7) <i>Chief Medical Officer</i>		668,750	668,750	2.6%
George Esgro(8) <i>Vice President Sales and Marketing</i>				*
Alastair McEwan(9) <i>Director</i>		1,125,000	1,125,000	4.3%
All directors and executive officers as a group (6 persons, consisting of 5 officers and 1 non-employee director)	17,045,000	2,617,500	19,662,500	71.4%

\* Represents beneficial ownership of less than one percent of common stock.



- (1) Unless otherwise indicated, the address of each beneficial owner is care of Cornerstone BioPharma Holdings, Inc., 2000 Regency Parkway, Suite 255 Cary, NC 27511.
- (2) Consists of shares underlying a warrant to purchase common stock issued to ProPharm Investments, LLC in July 2006. The warrant exercise price is \$50,000 and the warrant is exercisable for a number of shares such that after issuance of the warrant shares, ProPharm Investments, LLC will own 5% of Cornerstone's outstanding common stock as of the date of the warrant is surrendered to Cornerstone. The shares listed assume that the number of shares of Cornerstone common stock outstanding on the date of warrant exercise is the same as the number of shares of Cornerstone common stock outstanding on June 30, 2008. The right to exercise the warrant will terminate as of the effective time of the merger. Cornerstone is required to give ProPharm Investments, LLC advance notice of the proposed merger so that ProPharm Investments, LLC can determine whether to exercise its option to purchase shares under the warrant in advance of the effective time.
- (3) Consists of 13,450,000 shares of common stock held by Cornerstone BioPharma Holdings, Ltd. and options to purchase 300,000 shares of common stock pursuant to stock options grants awarded to Mr. Collard under Cornerstone's 2005 Stock Incentive Plan. Mr. Collard is the controlling stockholder and a director of Cornerstone BioPharma Holdings, Ltd. Mr. Collard disclaims beneficial ownership of the shares held by Cornerstone BioPharma Holdings, Ltd., except to the extent of his pecuniary interest therein.
- (4) Consists of 2,845,000 shares of common stock held by the Lutz Family Limited Partnership and options to purchase 256,250 shares and 25,000 shares of common stock pursuant to stock options grants awarded to Mr. Lutz under Cornerstone's 2005 Stock Incentive Plan and 2005 Stock Option Plan, respectively. Mr. Lutz has or shares voting and investment power over the shares of Cornerstone's common stock held by the Lutz Family Limited Partnership by virtue of his serving as general partner of the Lutz Family Limited Partnership. Mr. Lutz disclaims beneficial ownership of the shares held by the Lutz Family Limited Partnership, except to the extent of his pecuniary interest therein.
- (5) Consists of 3,100,000 shares of common stock and options to purchase 50,000 shares of common stock pursuant to stock options grants awarded to Mr. Baker under Cornerstone's 2005 Stock Incentive Plan.
- (6) Consists of 750,000 shares of restricted stock and options to purchase 202,500 shares and 40,000 shares of common stock pursuant to stock options grants awarded to Ms. Baldwin under Cornerstone's 2005 Stock Incentive Plan and 2005 Stock Option Plan, respectively.
- (7) Consists of options to purchase 668,750 shares of common stock pursuant to stock options grants awarded to Dr. Dickson under Cornerstone's 2005 Stock Incentive Plan.
- (8) 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 common stock. Cornerstone expects that the option award to Mr. Esgro will be completed immediately prior to the effective time of the merger.
- (9) Consists of options to purchase 1,125,000 shares of common stock pursuant to stock options grants awarded to Mr. McEwan under Cornerstone's 2005 Stock Incentive Plan.

**PRINCIPAL STOCKHOLDERS OF COMBINED COMPANY**

The following table and the related notes present certain information with respect to the beneficial ownership of the combined company upon consummation of the merger, by (1) each director and executive officer of the combined company, (2) each person or group who is known to the management of Critical Therapeutics and Cornerstone to become the beneficial owner of more than 5% of the common stock of the combined company upon the consummation of the merger and (3) all directors and executive officers of the combined company as a group. Unless otherwise indicated in the footnotes to this table and subject to the voting agreements entered into by directors and executive officers of Critical Therapeutics and Cornerstone, Critical Therapeutics and Cornerstone believe that each of the persons named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

The percent of common stock of Critical Therapeutics is based on 43,370,448 shares of common stock outstanding as of June 30, 2008. The percent of common stock of Cornerstone is based on 24,926,150 shares of common stock outstanding as of June 30, 2008. The percent of common stock of the combined company is based on 125,658,692 shares of common stock of the combined company outstanding upon the consummation of the merger and assumes, among other things, that the merger is consummated on June 30, 2008, that the exchange ratio of Cornerstone common stock will be 2.513072 shares of Critical Therapeutics stock for each share of Cornerstone s common stock, that ProPharm Investments, LLC exercises its warrant rights in advance of the proposed merger to purchase all shares of Cornerstone s common stock it is entitled to purchase under its warrant agreement with Cornerstone and that the Carolina Note is converted into 6,491,034 shares of Cornerstone s common stock immediately before the effective time of the merger. Shares of Critical Therapeutics common stock subject to options and warrants that are currently exercisable or are exercisable within 60 days after June 30, 2008, are treated as outstanding and beneficially owned by the person holding them for the purpose of computing the percentage ownership of Critical Therapeutics common stock of that person but are not treated as outstanding for the purpose of computing the percentage ownership of Critical Therapeutics common stock of any other person. Shares of Cornerstone s common stock subject to options or warrants that are currently exercisable or are exercisable within 60 days of June 30, 2008 will be automatically converted at the effective time of the merger into the right to receive Critical Therapeutics common stock in lieu of Cornerstone s common stock and are treated as outstanding and beneficially owned by the person holding them for the purpose of computing the percentage ownership of common stock of the combined company of that person but are not treated as outstanding for the purpose of computing the percentage ownership of common stock of the combined company of any other stockholder. All share numbers in this table are subject to adjustment to account for the reverse stock split.

Name and Address of Beneficial Owner(1)	Number of Outstanding Shares Beneficially Owned	Shares Underlying Warrants Currently Exercisable	Shares Underlying Options Exercisable within 60 Days	Total Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned
	<b>5% Stockholders</b>				
Craig A. Collard(2)	50,113,252		753,921	50,867,173	40.2%

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*President and Chief Executive*

Officer and Director

Cornerstone Biopharma Holdings,

Ltd.	33,800,817		33,800,817	26.9%
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Carolina Pharmaceuticals Ltd.	16,312,435		16,312,435	13.0%
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Steven M. Lutz(3)	7,149,689	706,801	7,856,490	6.2%
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*Executive Vice President,*

Commercial Operations

Lutz Family Limited Partnership	7,149,689		7,149,689	5.7%
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James V. Baker(4)	7,790,523	125,653	7,916,176	6.3%
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***Other Directors and Named***

***Executive Officers***

Name and Address of Beneficial Owner(1)	Number of Outstanding Shares Beneficially Owned	Shares Underlying Warrants Currently Exercisable	Shares Underlying Options Exercisable within 60 Days	Total Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned
	Chenyqua Baldwin(5) <i>Vice President, Finance</i>	1,884,803		609,419	2,494,222
Brian Dickson, M.D.(6) <i>Chief Medical Officer</i>			1,680,616	1,680,616	1.3%
George Esgro(7) <i>Vice President Sales and Marketing</i>					*
Alastair McEwan(8) <i>Director</i>			2,827,205	2,827,205	2.2%
All directors and executive officers as a group (6 persons, consisting of 5 officers and 1 non-employee director)	59,147,744		6,577,962	65,725,706	49.7%

\* Represents beneficial ownership of less than one percent of common stock.

- (1) Unless otherwise indicated, the address of each beneficial owner is care of Cornerstone BioPharma Holdings, Inc., 2000 Regency Parkway, Suite 255 Cary, NC 27511.
- (2) Consists of 33,800,817 shares of common stock held by Cornerstone BioPharma Holdings, Ltd., 16,312,435 shares of common stock held by Carolina Pharmaceuticals received in connection with the conversion of the outstanding principal amount under the Carolina Note and options to purchase 753,921 shares of common stock pursuant to stock options grants awarded to Mr. Collard under Cornerstone's 2005 Stock Incentive Plan. Mr. Collard is the controlling stockholder and a director of each of Cornerstone BioPharma Holdings, Ltd. and Carolina Pharmaceuticals. Mr. Collard disclaims beneficial ownership of the shares held by Cornerstone BioPharma Holdings, Ltd. and Carolina Pharmaceuticals, except to the extent of his pecuniary interest therein.
- (3) Consists of 7,149,689 shares of common stock held by the Lutz Family Limited Partnership and options to purchase 643,975 shares and 62,827 shares of common stock pursuant to stock options grants awarded to Mr. Lutz under Cornerstone's 2005 Stock Incentive Plan and 2005 Stock Option Plan, respectively. Mr. Lutz has or shares voting and investment power over the shares of Cornerstone's common stock held by the Lutz Family Limited Partnership by virtue of his serving as general partner of the Lutz Family Limited Partnership. Mr. Lutz disclaims beneficial ownership of the shares held by the Lutz Family Limited Partnership, except to the extent of his pecuniary interest therein.
- (4) Consists of 7,790,523 shares of common stock and options to purchase 125,653 shares of common stock pursuant to stock options grants awarded to Mr. Baker under Cornerstone's 2005 Stock Incentive Plan.

- (5) Consists of 1,884,803 shares of restricted stock and options to purchase 508,897 shares and 100,523 shares of common stock pursuant to stock options grants awarded to Ms. Baldwin under Cornerstone's 2005 Stock Incentive Plan and 2005 Stock Option Plan, respectively.
- (6) Consists of options to purchase 1,680,616 shares of common stock pursuant to stock options grants awarded to Dr. Dickson under Cornerstone's 2005 Stock Incentive Plan.
- (7) 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 common stock. Cornerstone expects that the option award to Mr. Esgro will be completed immediately prior to the effective time of the merger but that none of the options will be currently exercisable or exercisable within 60 days of the effective time of the merger.
- (8) Consists of options to purchase 2,827,205 shares of common stock pursuant to stock options grants awarded to Mr. McEwan under Cornerstone's 2005 Stock Incentive Plan.

## LEGAL MATTERS

Wilmer Cutler Pickering Hale and Dorr LLP, New York, New York, will pass upon the validity of the Critical Therapeutics common stock offered by this proxy statement/prospectus. Partners of Wilmer Cutler Pickering Hale and Dorr LLP beneficially own 19,020 shares of Critical Therapeutics common stock.

## EXPERTS

The consolidated financial statements of Critical Therapeutics, Inc. as of December 31, 2007 and 2006 and for each of the three years in the period ended December 31, 2007, included in this proxy statement/prospectus, and the related financial statement schedule included elsewhere in the registration statement of which this proxy statement/prospectus forms a part have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein (which report expresses an unqualified opinion on the financial statements and includes explanatory paragraphs referring to Critical Therapeutics, Inc.'s adoption of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, effective January 1, 2006 and the uncertainty relating to Critical Therapeutics, Inc.'s ability to continue as a going concern). Such consolidated financial statements and financial statement schedule have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

The consolidated financial statements of Cornerstone Biopharma Holdings, Inc. as of December 31, 2007 and 2006, and for each of the years ended December 31, 2005, 2006 and 2007, included in this proxy statement/prospectus, have been audited by Grant Thornton LLP, independent registered public accountants, as indicated in their report with respect thereto and such consolidated financial statements are included herein in reliance upon the authority of said firm as experts in giving said report.

## WHERE YOU CAN FIND MORE INFORMATION

Critical Therapeutics files reports, proxy statements and other information with the SEC as required by the Exchange Act. You can find, copy and inspect information Critical Therapeutics files at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can call the SEC at 1-800-SEC-0330 for further information about the public reference room. You can review Critical Therapeutics' electronically filed reports, proxy and information statements on the SEC's web site at <http://www.sec.gov> or on Critical Therapeutics' web site at <http://www.crtx.com>. Information included on Critical Therapeutics' web site is not a part of this proxy statement/prospectus.

You should rely only on the information contained in this proxy statement/prospectus or on information to which Critical Therapeutics has referred you. Critical Therapeutics has not authorized anyone else to provide you with any information. Critical Therapeutics provided the information concerning Critical Therapeutics, and Cornerstone provided the information concerning Cornerstone, appearing in this proxy statement/prospectus.

This proxy statement/prospectus is part of a registration statement that Critical Therapeutics filed with the SEC. The registration statement contains more information than this proxy statement/prospectus regarding Critical Therapeutics and the securities, including exhibits and schedules. You can obtain a copy of the registration statement from the SEC at any address listed above or from the SEC's web site.

**INDEX TO CRITICAL THERAPEUTICS CONSOLIDATED FINANCIAL STATEMENTS**

**TABLE OF CONTENTS**

	<b>Page</b>
<b>CRITICAL THERAPEUTICS CONSOLIDATED FINANCIAL STATEMENTS</b>	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets at December 31, 2007 and December 31, 2006	F-3
Consolidated Statements of Operations for the Years ended at December 31, 2007, December 31, 2006 and December 31, 2005	F-4
Consolidated Statements of Stockholders' Equity and Comprehensive Loss for the Years ended at December 31, 2007, December 31, 2006 and December 31, 2005	F-5
Consolidated Statements of Cash Flows for the Years ended at December 31, 2007, December 31, 2006 and December 31, 2005	F-6
Notes to Consolidated Financial Statements	F-7
Critical Therapeutics Condensed Consolidated Financial Statements (Unaudited)	
Condensed Consolidated Balance Sheets at March 31, 2008 and December 31, 2007 (Unaudited)	F-36
Condensed Consolidated Statements of Operations for the Three months ended March 31, 2008 and 2007 (Unaudited)	F-37
Condensed Consolidated Statements of Cash Flows for the Three months ended March 31, 2008 and 2007 (Unaudited)	F-38
Notes to Unaudited Condensed Consolidated Financial Statements	F-39

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
Critical Therapeutics, Inc.  
Lexington, Massachusetts

We have audited the accompanying consolidated balance sheets of Critical Therapeutics, Inc. and subsidiary (the Company ) as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders equity and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2007. Our audits also included the financial statement schedule listed in the Index at Item 21. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Critical Therapeutics, Inc. and subsidiary as of December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations, recurring negative cash flows from operations and had an accumulated deficit of \$191.4 million as of December 31, 2007. The Company expects to incur substantial losses for the foreseeable future as a result of research, development and commercial expenditures. These matters raise substantial doubt about the Company s ability to continue as a going concern. Management s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for stock-based compensation on January 1, 2006 as required by Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*.

/s/

DELOITTE & TOUCHE LLP

Boston, Massachusetts  
March 27, 2008





**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS**

**December 31,**  
**2007                      2006**  
**(In thousands, except**  
**share and per share data)**

**ASSETS:**

Current assets:		
Cash and cash equivalents	\$ 33,828	\$ 48,388
Accounts receivable, net	1,273	877
Amount due under collaboration agreements	31	650
Short-term investments		650
Inventory	5,599	4,048
Prepaid expenses and other	2,174	980
 Total current assets	 42,905	 55,593
 Fixed assets, net	 1,151	 2,421
Other assets	868	168
 Total assets	 \$ 44,924	 \$ 58,182

**LIABILITIES AND STOCKHOLDERS EQUITY:**

Current liabilities:		
Current portion of long-term debt and capital lease obligations	\$ 370	\$ 1,012
Accounts payable	5,283	1,049
Accrued compensation	2,051	1,865
Accrued expenses	5,103	2,076
Current portion of accrued license fees	1,838	
Current portion of deferred co-promotion fees	1,880	
Deferred collaboration revenue		675
Deferred product revenue		1,178
 Total current liabilities	 16,525	 7,855
 Long-term debt and capital lease obligations, less current portion		421
Long-term portion of accrued license fees, less current portion	1,754	
Long-term portion of deferred co-promotion fees	9,554	
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, par value \$0.001; authorized 5,000,000 shares; no shares issued and outstanding		
Common stock, par value \$0.001; authorized 90,000,000 shares; issued and outstanding 42,805,348 shares and 42,345,642 shares at December 31, 2007 and	43	43

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2006, respectively		
Additional paid-in capital	208,420	204,378
Deferred stock-based compensation		(99)
Accumulated deficit	(191,372)	(154,399)
Accumulated other comprehensive loss		(17)
Total stockholders' equity	17,091	49,906
Total liabilities and stockholders' equity	\$ 44,924	\$ 58,182

The accompanying notes are an integral part of these consolidated financial statements.

F-3

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except share and per share data)</b>		
<b>Revenues:</b>			
Net product sales	\$ 11,008	\$ 6,647	\$ 387
Revenue under collaboration and license agreements	1,861	6,431	5,837
<b>Total revenues</b>	<b>12,869</b>	<b>13,078</b>	<b>6,224</b>
<b>Costs and expenses:</b>			
Cost of products sold	4,233	2,222	514
Research and development	21,655	26,912	29,959
Sales and marketing	12,193	18,284	13,671
General and administrative	13,572	13,456	11,406
Restructuring charges		3,498	
<b>Total costs and expenses</b>	<b>51,653</b>	<b>64,372</b>	<b>55,550</b>
Operating loss	(38,784)	(51,294)	(49,326)
<b>Other income (expense):</b>			
Interest income	2,020	2,726	2,427
Interest expense	(209)	(214)	(191)
<b>Total other income</b>	<b>1,811</b>	<b>2,512</b>	<b>2,236</b>
<b>Net loss</b>	<b>\$ (36,973)</b>	<b>\$ (48,782)</b>	<b>\$ (47,090)</b>
<b>Net loss per share</b>	<b>\$ (0.87)</b>	<b>\$ (1.37)</b>	<b>\$ (1.61)</b>
<b>Basic and diluted weighted-average common shares outstanding</b>	<b>42,580,884</b>	<b>35,529,048</b>	<b>29,276,243</b>

The accompanying notes are an integral part of these consolidated financial statements.

## CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE LOSS  
YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

	Accumulated						
	Common Stock	Additional Paid-In Capital	Deferred Stock- Based Compensation	Accumulated Deficit	Other Comprehensive Loss	Total Stockholder Equity	Comprehensive Loss
	(In thousands, except share data)						
<b>BALANCE January 1, 2005</b>	\$ 24	\$ 130,374	\$ (6,101)	\$ (58,527)	\$ (362)	\$ 65,408	
Issuance of 96,235 shares of common stock, upon exercise of options under stock purchase plan		158				158	
Deferred stock-based compensation to non-employees		(458)	458				
Amortization of deferred stock-based compensation			2,141			2,141	
Reversal of deferred stock based compensation		(221)	221				
Issuance of 9,945,261 shares of common stock and warrants to purchase 3,480,842 shares of common stock in private placement, net of \$3.1 million in placement fees	10	51,352				51,362	
Grant of stock options to non-employees		513	(513)				
Net loss				(47,090)		(47,090)	\$ (47,090)
Unrealized gain on investments					268	268	268
Comprehensive loss							\$ (46,822)
<b>BALANCE December 31, 2005</b>	34 1	181,718 613	(3,794)	(105,617)	(94)	72,247 614	

Issuance of 752,241 shares of common stock, upon exercise of options under stock purchase plan							
Issuance of common stock to employees under stock purchase plan		22				22	
Deferred stock-based compensation to non-employees		(904)	904				
Amortization of deferred stock-based compensation				105		105	
Reversal of deferred stock based compensation in adopting SFAS No. 123(R)		(2,686)	2,686				
Issuance of 7,455,731 shares of common stock and warrants to purchase 3,727,865 of common stock in a registered offering, net of \$1.5 million in issuance costs	7	18,479				18,486	
Restricted stock buyback		(1)				(1)	
Issuance of restricted stock	1					1	
Stock-based compensation to employees		7,137				7,137	
Net loss				(48,782)		(48,782)	\$ (48,782)
Unrealized gain on investments					77	77	77
Comprehensive loss							\$ (48,705)
<b>BALANCE</b>							
<b>December 31, 2006</b>	43	204,378	(99)	(154,399)	(17)	49,906	
Issuance of 419,557 shares of common stock, upon exercise of options and vested restricted stock		147				147	
Deferred stock-based compensation to non-employees		(74)	74				
			22			22	

Amortization of deferred stock-based compensation					
Reversal of deferred stock-based compensation	(3)	3			
Issuance of common stock to employees under stock-purchase plan	63			63	
Stock-based compensation to employees and non-employees	3,909			3,909	
Net loss			(36,973)	(36,973)	\$ (36,973)
Unrealized gain on investments			17	17	17
Comprehensive loss					\$ (36,956)
<b>BALANCE</b>					
<b>December 31, 2007</b>	\$ 43	\$ 208,420	\$ (191,372)	\$ 17,091	

The accompanying notes are an integral part of these consolidated financial statements.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands)</b>		
Cash flows from operating activities:			
Net loss	\$ (36,973)	\$ (48,782)	\$ (47,090)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	531	939	800
Accretion (amortization) of premiums on short-term investments and other	114	(69)	903
Loss on disposal of fixed assets and other	385	86	149
Non-cash restructuring charge		1,109	
Lease abandonment charge	426		
Preferred stock received in license agreement, net	(400)		
Stock-based compensation expense	3,931	6,620	2,141
Changes in assets and liabilities:			
Accounts receivable	(396)	140	(1,024)
Amount due under collaboration agreements	619	(445)	(189)
Inventory	(1,551)	(2,179)	(1,869)
Prepaid expenses and other	(1,194)	1,199	(283)
Accounts payable	4,234	(3,566)	397
Accrued expenses	2,787	(935)	2,135
Accrued license fees	3,495		
Deferred collaboration revenue	(675)	(5,031)	(2,837)
Deferred product revenue	(1,178)	(529)	1,707
Deferred co-promotion fees	11,434		
Net cash used in operating activities	(14,411)	(51,443)	(45,060)
Cash flows from investing activities:			
Proceeds from sale of fixed assets	371		
Purchases of fixed assets	(17)	(370)	(2,182)
Proceeds from sales and maturities of short-term investments	650	36,859	72,915
Purchases of investments	(300)	(11,802)	(32,255)
Net cash provided by investing activities	704	24,687	38,478
Cash flows from financing activities:			
Net proceeds from private placement of common stock		18,486	51,362
Proceeds from the issuance of common stock and other	210	636	158
Proceeds from long-term debt			1,300
Repayments of long-term debt and capital lease obligation	(1,063)	(1,235)	(961)



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Net cash (used in) provided by financing activities	(853)	17,887	51,859
Net (decrease) increase in cash and cash equivalents	(14,560)	(8,869)	45,277
Cash and cash equivalents at beginning of year	48,388	57,257	11,980
Cash and cash equivalents at end of year	\$ 33,828	\$ 48,388	\$ 57,257
Supplemental disclosures of cash flow information:			
Cash paid during the period for:			
Interest	\$ 120	\$ 221	\$ 172
Non-cash investing and financing activities:			
Fixed assets acquired under capital lease obligation	\$	\$	\$ 125

The accompanying notes are an integral part of these consolidated financial statements.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(1) Basis of Presentation**

Critical Therapeutics, Inc. (the Company) is a biopharmaceutical company focused on the development and commercialization of products designed to treat respiratory, inflammatory and critical care diseases linked to the body's inflammatory response. The Company was incorporated in the state of Delaware on July 14, 2000 under the name Medicept, Inc. On March 12, 2001, the Company changed its name from Medicept, Inc. to Critical Therapeutics, Inc. The Company formed a wholly-owned subsidiary, CTI Securities Corporation, a Massachusetts corporation, in 2003.

The Company is subject to a number of risks similar to other companies in the biopharmaceutical industry, including, but not limited to, risks and uncertainties related to the progress, timing and success of the Company's regulatory filings, regulatory approvals and product launches, including ZYFLO CR<sup>®</sup> (zileuton) extended-release tablets (ZYFLO CR); the Company's ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize ZYFLO CR; the market acceptance and future sales of ZYFLO CR; the progress and timing of the Company's drug development programs and related clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the Company's ability to obtain, maintain and enforce patent and other intellectual property protection for ZYFLO CR, ZYFLO<sup>®</sup> (zileuton) tablets (ZYFLO), its discoveries and drug candidates; the Company's ability to successfully enter into additional strategic co-promotion, collaboration or licensing transactions on favorable terms, if at all; the Company's ability to obtain additional financing to conduct research, development and commercialization activities; and the Company's compliance with governmental and other regulations.

***Management's Plans***

Since the Company's inception, it has incurred significant losses each year. As of December 31, 2007, the Company had an accumulated deficit of \$191.4 million. The Company expects to incur significant losses for the foreseeable future and it may never achieve profitability. Although the size and timing of its future operating losses are subject to significant uncertainty, the Company expects its operating losses to continue over the next several years as it funds its development programs, markets and sells ZYFLO CR and prepares for the potential commercial launch of its product candidates. Since the Company's inception, it has raised proceeds to fund its operations through public offerings of common stock, private placements of equity securities, debt financings, the receipt of interest income, payments from its collaborators MedImmune and Beckman Coulter license fees from Innovative Metabolics, Inc. (IMI), payments from DEY under its zileuton co-promotion agreement and revenue from sales of ZYFLO and ZYFLO CR.

In November 2007, the Company's board of directors announced that it is in the process of reviewing a range of strategic alternatives that could result in potential changes to the Company's current business strategy and future operations. As part of this process, the Company is considering alternatives to its current business strategy, and it has engaged an investment bank to advise it in considering its potential strategic alternatives. After concluding this review, it is possible that the Company could determine to pursue one or more of the strategic alternatives that it is considering or a variation of one of these alternatives. Pending any decision to change strategic direction, the Company is continuing its commercial and development activities in accordance with its existing business strategy with an increased focus on its cash position. As a result of this review, the extent of the Company's future capital requirements is difficult to assess.

For the year ended December 31, 2007, the Company's net cash used in operating activities was \$14.4 million. If the Company's existing resources are insufficient to satisfy its liquidity requirements, either under its current operating plan or any new operating plan it may adopt, it may need to raise additional external funds through collaborative arrangements and public or private financings. Additional financing may not be available to the Company on acceptable terms or at all.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Going Concern Assumption***

The Company has experienced significant operating losses in each year since its inception in 2000 and 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. As of December 31, 2007, the Company had an accumulated deficit of approximately \$191.4 million. For the year ended December 31, 2007, it recorded \$11.0 million of revenue from the sale of ZYFLO and ZYFLO CR and has not recorded revenue from any other product. Management expects that the Company will continue to incur substantial losses for the foreseeable future from spending significant amounts to fund the Company's research, development and commercialization efforts. These matters raise substantial doubt about the Company's ability to continue as a going concern and, therefore, the Company may be unable to realize its assets and discharge its liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts nor to amounts and classification of liabilities that may be necessary should the Company be unable to continue as a going concern.

**(2) Summary of Significant Accounting Policies**

***Basis of Presentation***

The consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiary, CTI Securities Corporation. All intercompany balances and transactions have been eliminated.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in these financial statements include certain judgments regarding revenue recognition, product returns, inventory valuation, accrued and prepaid expenses and valuation of stock-based compensation.

***Cash Equivalents***

The Company considers all highly-liquid investments with original maturities of three months or less when purchased to be cash equivalents.

***Investments***

Short-term investments consist primarily of U.S. government treasury and agency notes, commercial paper, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, each of investment-grade quality, which have an original maturity date greater than 90 days that can be sold within one year. These securities are held until such time as the Company intends to use them to meet the ongoing liquidity needs to support its operations. These investments are recorded at fair value and accounted for as available-for-sale securities. The unrealized gain (loss) during the period is recorded within accumulated other comprehensive loss unless it is

determined to be other-than-temporary. During the years ended December 31, 2007, 2006 and 2005, the Company recorded a net unrealized gain on short-term investments of \$17,000, \$77,000 and \$268,000, respectively. The original cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization or accretion is included in interest income (expense).

The unrealized losses as of December 31, 2006 were primarily caused by interest rate increases. The following table shows, for the years ended December 31, 2007 and 2006, the gross unrealized gains and losses and the

F-8

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## CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

fair value of the Company's investments with unrealized gains and losses that are not deemed to be other-than-temporary, aggregated by investment category. There were no available-for-sale securities held as of December 31, 2007.

	Amortized Cost	As of December 31, 2006		Fair Value
		Unrealized Gains	Unrealized Losses	
		(In thousands)		
Cash and cash equivalents:				
Cash	\$ 12,840	\$	\$	\$ 12,840
Commercial paper	32,678	1	(18)	32,661
Money market mutual funds	2,887			2,887
Cash and cash equivalents	48,405	1	(18)	48,388
Short-term investments:				
Auction rate securities	650			650
Short-term investments	650			650
Cash and cash equivalents and short-term investments	\$ 49,055	\$	\$	\$ 49,038

At December 31, 2007, the Company held \$300,000 in auction rate securities with a AAA credit rating upon purchase. In February 2008, the Company was informed that there was insufficient demand at auction for these securities. As a result, this amount is currently not liquid and may not become liquid unless the Company is able to refinance it. The Company has classified its \$300,000 in auction rate securities as a long-term investment and has included the amount in other assets on the Company's accompanying balance sheet.

***Inventory***

Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out (FIFO) method. The Company analyzes its inventory levels quarterly and reserves for inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. Expired inventory is disposed of and the related costs are expensed in the period.

***Fixed Assets***

Fixed assets are stated at cost, net of accumulated depreciation and amortization. Depreciation is computed on a straight-line basis over estimated useful lives commencing upon the date the assets are placed in service. Upon retirement or sale, the cost of the assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in operating income. Repairs and maintenance costs are expensed

as incurred. The useful lives for our major asset categories are as follows:

<b>Asset Description</b>	<b>Useful Life (Years)</b>
Furniture and fixtures	7
Office equipment	5
Lab equipment	5
Computer hardware and software	3

Leasehold improvements are amortized over the shorter of the useful life of the asset or the lease term.

F-9

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Impairment of Long-Lived Assets***

Long-lived assets and, if and when applicable, certain identifiable intangibles held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In performing the review for recoverability, the Company will estimate the future cash flows expected to result from the use of the asset and its eventual disposition. If the sum of the expected future cash flows (undiscounted and without interest charges) is less than the carrying amount of the asset, an impairment loss is recognized. Measurement of an impairment loss for long-lived assets and identifiable intangibles that the Company expects to hold and use is based on the fair value of the asset. Assets that are being held for sale are recorded at the lower of carrying value or fair value less cost to sell. At December 31, 2007, assets held-for-sale had a fair value of approximately \$167,000 and are included in fixed assets in the accompanying consolidated balance sheet. In 2007, the Company accelerated depreciation and recorded an impairment charge of \$275,000 resulting from the Company's decision to cease its in-house research activities (see Note 16). In 2006, the Company recorded an impairment charge of approximately \$488,000 related to computer and laboratory equipment as a result of its 2006 restructurings (See Note 15).

***Research and Development***

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for monitoring and analyzing clinical trials, regulatory costs, including user fees paid to the FDA, milestone payments to third parties, costs related to the development of the Company's NDA for ZYFLO CR, costs of contract research and manufacturing and the cost of facilities. In addition, research and development expenses include the cost of the Company's medical affairs and medical information functions, which educate physicians on the scientific aspects of its commercial products and the approved indications, labeling and the costs of monitoring adverse events. The Company expenses research and development costs and patent related costs as incurred. Because of the Company's ability to utilize resources across several projects, many of its research and development costs are not tied to any particular project and are allocated among multiple projects. The Company records direct costs on a project-by-project basis. The Company records indirect costs in the aggregate in support of all research and development. Development costs for clinical development stage programs tend to be higher than earlier stage programs due to the costs associated with conducting clinical trials and large-scale manufacturing. After FDA approval of a product candidate, manufacturing expenses associated with a product will be recorded as cost of products sold rather than as research and development expenses.

***Revenue Recognition and Deferred Revenue***

The Company recognizes revenue in accordance with the SEC Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* (SAB 101) as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104). Specifically, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. The Company's revenue is currently derived from product sales of its commercially marketed products, ZYFLO and ZYFLO CR and its collaboration and license agreements. The collaboration and license agreements provide for various payments, including research and development funding, license fees, milestone payments and royalties. In addition, the Company's product sales are subject to various rebates, discounts and



incentives that are customary in the pharmaceutical industry.

*Net product sales*

The Company sells ZYFLO CR and ZYFLO primarily to pharmaceutical wholesalers, distributors and pharmacies. The Company commercially launched ZYFLO in October 2005 and ZYFLO CR in September

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

2007. The Company authorizes returns for damaged products and exchanges for expired products in accordance with its return goods policy and procedures, and has established allowances for such amounts at the time of sale. The Company is obligated to accept from customers the return of products that are within six months of their expiration date or up to 12 months beyond their expiration date. The Company recognizes revenue from product sales in accordance with Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists*, which requires the amount of future returns to be reasonably estimated at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns, estimated rebates in connection with contracts relating to managed care, Medicaid, Medicare, and estimated chargebacks from distributors and prompt payment and other discounts.

The Company establishes allowances for estimated product returns, rebates and chargebacks primarily based on several factors, including the actual historical product returns, the Company's estimate of inventory levels of products in the distribution channel, the shelf-life of the product shipped, competitive issues such as new product entrants and other known changes in sales trends. The Company evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve accordingly.

Prior to the first quarter of 2007, the Company deferred the recognition of revenue on ZYFLO product shipments to wholesale distributors until units were dispensed through patient prescriptions as the Company was unable to reasonably estimate the amount of future product returns. Units dispensed are not generally subject to return. In the first quarter of 2007, the Company began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties as sufficient history exists to make such estimates. In connection with this change in estimate, the Company recorded an increase in net product sales in the year ended December 31, 2007 related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. This change in estimate totaled approximately \$953,000 and was reported in the Company's results for the first quarter of 2007. In September 2007, the Company launched ZYFLO CR and recorded \$2.3 million in product sales of ZYFLO CR in the second half of 2007 as a result of the launch. The Company anticipates that the rate of return for ZYFLO CR will be comparable to the rate of return used for ZYFLO. As a result, the Company recognizes revenue for sales of ZYFLO CR upon shipment to third parties and records a reserve for estimated returns. As of December 31, 2007, the Company's allowances for ZYFLO CR and ZYFLO product returns were \$177,000 and \$696,000, respectively. Included in the ZYFLO allowance was \$605,000 related to product the Company does not expect to be dispensed by third parties through patient prescriptions in the first quarter of 2008 as a result of its conversion to ZYFLO CR.

At December 31, 2007, the Company's accounts receivable balance of \$1.3 million was net of allowances of \$29,000. At December 31, 2006, the Company's accounts receivable balance of \$877,000 was net of allowances of \$24,000.

***Revenue under collaboration and license agreements***

Under the Company's collaboration agreements with MedImmune and Beckman Coulter, the Company is entitled to receive non-refundable license fees, milestone payments and other research and development payments. Payments received are initially deferred from revenue and subsequently recognized in the Company's statements of operations when earned. The Company must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by the Company's collaborators. The Company recognizes these revenues over the estimated performance period as set forth in the

contracts based on proportional performance adjusted from time to time for any delays or acceleration in the development of the product. For example, a delay or acceleration of the performance period by the Company's collaborator may result in further deferral of revenue or the acceleration of revenue previously deferred. Because MedImmune and

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Beckman Coulter can each cancel its agreement with the Company, the Company does not recognize revenues in excess of cumulative cash collections.

Under the Company's license agreement with IMI, the Company licensed to IMI patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. Under the agreement with IMI, the Company received an initial license fee of \$500,000 in cash junior and IMI preferred stock valued at \$500,000 in connection with IMI's first financing. However, under its license agreement with The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute) (The Feinstein Institute), the Company was obligated to pay to The Feinstein Institute \$100,000 of this cash payment and IMI junior preferred stock valued at \$100,000. The Company included in revenue under collaboration and license agreements for the year ended December 31, 2007, the \$1.0 million total initial license fee that the Company received from IMI and included the payments of \$100,000 in cash and IMI junior preferred stock valued at \$100,000 that the Company made to The Feinstein Institute in research and development expenses. These amounts were recorded in the second quarter of 2007. Under the license agreement, IMI also has agreed to pay the Company \$1.0 million, excluding a \$200,000 payment that the Company would be obligated to pay to The Feinstein Institute, upon full regulatory approval of a licensed product by the FDA or a foreign counterpart agency and royalties based on net sales of licensed products and methods by IMI and its affiliates.

***Fair Value of Financial Instruments***

The carrying amounts of the Company's financial instruments, which include cash equivalents, short-term investments, accounts receivable, accounts payable, long-term debt, capital lease obligations, and auction rate securities included in other assets approximate their fair values.

***Concentrations of Credit Risk and Limited Suppliers***

SFAS No. 105, Disclosure of Information about Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk, requires disclosure of any significant off-balance-sheet and credit risk concentrations. The Company has no off-balance-sheet or concentrations of credit risk related to foreign exchange contracts, options contracts or other foreign hedging arrangements.

The financial instruments that potentially subject the Company to concentrations of credit risk are cash, cash equivalents, short-term investments and accounts receivable. The Company's cash and cash equivalents are maintained with highly-rated commercial banks and are monitored against the Company's investment policy, which limits concentrations of investments in individual securities and issuers.

The Company relies on certain materials used in its development and manufacturing processes, some of which are procured from a single source. The Company purchases the zileuton active pharmaceutical ingredient pursuant to a long-term supply agreement with one supplier. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development or commercialization process and thereby adversely affect the Company's operating results. In addition, a disruption in the commercial supply of ZYFLO CR or a significant increase in the cost of the active pharmaceutical ingredient from these sources could have a material adverse effect on the Company's business, financial position and results of operations.

The Company sells primarily to large national wholesalers, which in turn, may resell the product to smaller or regional wholesalers, retail pharmacies or chain drug stores. The following tables summarize the number of customers that individually comprise greater than 10% of total billings, some of which have been recognized as revenue in 2007 and 2006, and their aggregate percentage of the Company's total billings for the years ended December 31, 2007, 2006 and 2005 and the number of customers that comprise more than 10% of total

F-12

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

accounts receivable and their aggregate percentage of the Company's total accounts receivable at December 31, 2007 and 2006:

	<b>Year Ended December 31</b>		
	<b>2007 Billings</b>	<b>2006 Billings</b>	<b>2005 Billings</b>
Company A	39%	40%	26%
Company B	37%	37%	29%
Company C	19%	18%	30%
Total	95%	95%	85%

	<b>December 31,</b>	
	<b>2007 Accounts Receivable</b>	<b>2006 Accounts Receivable</b>
Company A	65%	42%
Company B	15%	19%
Company C	15%	37%
Total	95%	98%

***Income Taxes***

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have previously been included in either the Company's consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial accounting and tax bases of assets and liabilities using tax rates expected to be in effect for the year in which the differences are expected to reverse. A valuation allowance is provided against net deferred tax assets where management believes it is more likely than not that the asset will not be realized. In 2007, the Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109* (FIN 48), which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FAS 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The adoption of FIN 48 did not impact the Company's financial condition, results of operations, or cash flows.

***Stock-Based Compensation***

Prior to January 1, 2006, the Company accounted for stock-based awards to employees using the intrinsic-value method as prescribed by Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB No. 25 ), and related interpretations and the disclosure provisions of SFAS 123. Accordingly, no compensation expense was recorded for options issued to employees in fixed amounts and with fixed exercise prices at least equal to the fair market value of the Company's common stock at the date of grant. Conversely, when the exercise price for accounting purposes was below fair value of the Company's common stock on the date of grant, a non-cash charge to compensation expense was recorded ratably over the term of the option vesting period in an amount equal to the difference between the value calculated using the exercise price and the fair value. The Company issued options prior to March 19, 2004, the date it filed its initial registration statement on Form S-1 ( Form S-1 ), with the SEC, at values less than deemed fair market value. This resulted in recording deferred compensation, which has been recognized into operating expenses over the respective vesting periods.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Effective January 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payments* ( SFAS No. 123(R) ), using the modified prospective application method, which allows the Company to recognize compensation cost for granted, but unvested, awards, new awards and awards modified, repurchased, or cancelled after the required effective date. In addition, the Company elected the simplified method of calculating the Company's APIC Pool as prescribed by SFAS No. 123(R). Options granted to employees prior to the date of the initial Form S-1 filing continue to be accounted for under APB No. 25.

For the year ended December 31, 2005, had employee compensation expense been determined based on the fair value at the date of grant consistent with SFAS No. 123, the Company's pro forma net loss and pro forma net loss per share would have been as follows:

	<b>Year Ended December 31, 2005 (In thousands, except loss per share data)</b>
Net loss as reported	\$ (47,090)
Add: Stock-based compensation expense included in reported net loss	1,757
Deduct: Stock-based compensation expense determined under fair value method	(3,398)
Net loss pro forma	\$ (48,731)
Net loss per share (basic and diluted):	
As reported	\$ (1.61)
Pro forma	\$ (1.67)

Estimates of the fair value of equity awards will be affected by the market price of the Company's common stock, as well as certain assumptions used to value the equity awards. These assumptions include, but are not limited to, the expected volatility of the common stock risk free interest rate and the expected term of options granted. The Company has computed the impact under SFAS No. 123(R) for options granted and restricted stock issued using the Black-Scholes option-pricing model for the years ended December 31, 2007 and 2006. The Company increased its assumption for the year ended December 31, 2007 regarding expected volatility to 72%, from 61% in 2006 based on the Company's actual historical volatility since its initial public offering. In addition, the Company decreased its assumption for the year ended December 31, 2007 regarding the expected life of options to 6.1 years from 6.25 years in prior years. The expected life of options granted was estimated using the simplified method calculation as prescribed by SFAS No. 123(R). The assumptions used and weighted-average information are as follows:

**Year Ended December 31,**



	2007	2006	2005
Risk-free interest rate	4.4%	4.8%	4.1%
Expected dividend yield	0%	0%	0%
Expected life	6.1 years	6.25 years	4 years
Expected volatility	72%	61%	59%
Weighted-average fair value of options granted with exercise prices equal to fair value	\$ 1.43	\$ 2.58	\$ 3.26

All stock-based awards to non-employees are accounted for at their fair market value in accordance with SFAS No. 123(R) and Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, ( EITF No. 96-18 ). The Company periodically remeasures the fair value of the unvested portion of stock-

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

based awards to non-employees, resulting in charges or credits to operations in periods when such remeasurement occurs.

Because the Company has accumulated net operating losses as of December 31, 2007, option exercises may result in a tax deduction prior to the actual realization of the related tax benefit. As such, a tax benefit and a credit to additional paid-in capital for any tax deduction amount in excess of book compensation expense would not be recognized until the deduction reduces taxes payable.

***Basic and Diluted Loss per Share***

Basic and diluted net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share, because the effects of potentially dilutive securities are antidilutive for all periods presented. Antidilutive securities that are not included in the diluted net loss per share calculation aggregated 12,838,860, 12,992,960 and 9,809,751 as of December 31, 2007, 2006 and 2005, respectively. These antidilutive securities consist of outstanding stock options, warrants and unvested restricted common stock as of December 31, 2007, 2006 and 2005.

***Comprehensive Loss***

Comprehensive loss is the total of net loss and all other non-owner changes in equity. The difference between net loss, as reported in the accompanying consolidated statements of operations for the years ended December 31, 2007, 2006 and 2005, respectively, and comprehensive loss is the unrealized gain (loss) on available-for-sale investments for the period. Total comprehensive loss was \$37.0 million, \$48.7 million and \$46.8 million for the years ended December 31, 2007, 2006 and 2005, respectively. The unrealized gain (loss) on investments is the only component of accumulated other comprehensive loss in the accompanying consolidated balance sheets as of December 31, 2006.

***Disclosure about Segments of an Enterprise***

The Company follows the provisions of SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*. SFAS No. 131 establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS No. 131 also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions as to how to allocate resources and assess performance. The Company's chief operating decision maker, as defined under SFAS No. 131, is the chief executive officer. The Company believes it operates in one segment. All of the Company's revenues are generated in the United States and all assets are located in the United States.

***Recent Accounting Pronouncements***

In November 2007, the Financial Accounting Standards Board's (FASB) Emerging Issues Task Force (EITF) issued EITF Issue 07-01, *Accounting for Collaborative Arrangements*. EITF 07-01 requires collaborators to present the

results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF No. 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to Issue 01-9, *Accounting for Consideration Given by a Vendor to a Customer*. EITF

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

No. 07-01 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of EITF No. 07-01 to have a material impact on its financial statements and results of operations.

In June 2007, the EITF issued EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The initial adjustment to reflect the effect of applying this EITF as a change in accounting principle would be accounted for as a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. The Company does not expect the adoption of EITF No. 07-03 to have a material impact on its financial statements and results of operations.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, ( SFAS 141(R) ). SFAS 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values and changes other practices under SFAS No. 141, *Business Combinations*, some of which could have a material impact on how an entity accounts for its business combinations. SFAS 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008 and should be applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009. The provisions of SFAS 141(R) will only impact the Company if it is party to a business combination after the pronouncement has been adopted.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interest in Consolidated Financial Statements - an amendment of ARB No. 51* ( SFAS 160 ). SFAS 160 requires entities to report non-controlling minority interests in subsidiaries as equity in consolidated financial statements. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. SFAS 160 shall be applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for presentation and disclosure requirements, which shall be applied retrospectively for all periods presented. The Company does not expect the adoption of SFAS 160 to have a material impact on its financial statements and results of operations.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of SFAS 115* ( FAS 159 ). FAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. FAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which a company has chosen to use fair value on the face of the balance sheet. FAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company was required to adopt SFAS 159 on January 1, 2008. We do not expect the adoption of SFAS 159 will have a material effect on its consolidated financial position or results of operations.

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements* ( FAS 157 ). FAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. In February 2008, the FASB issued Staff Position No. FAS 157-2 ( FSP 157-2 ) that defers the effective date of applying the provisions of SFAS 157 to the fair value measurement of nonfinancial assets and nonfinancial liabilities until fiscal years beginning after November 15, 2008. The Company was required to adopt the provisions of SFAS 157 that pertain to

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

financial assets and liabilities on January 1, 2008. We do not expect the adoption of SFAS 157 will have a material impact on its consolidated financial position or results of operations. The Company is currently evaluating the effect FSP 157-2 will have on its consolidated financial position and results of operations.

**(3) Collaboration Agreements**

***MedImmune***

In July 2003, the Company entered into an exclusive license and collaboration agreement with MedImmune to jointly develop therapeutic products. Under the agreement, the Company has granted MedImmune an exclusive, worldwide royalty bearing license in exchange for a license fee, research funding, research and development milestone payments and royalties on product sales. The Company is required to perform certain research activities under an agreed upon research plan. The original term of the research plan was expected to be approximately 41 months, which began on July 30, 2003. In 2005, the Company changed its estimate of the term covered by the research plan to 47 months, which resulted in a decrease in revenue recognized of approximately \$237,000 in 2005. During the term of the research plan, the Company has received research funding from MedImmune based on the number of full-time equivalents employed by the Company for the purposes of executing the research plan. No performance is required of the Company subsequent to the research period. MedImmune will be responsible for subsequent product development and commercialization. All payments made to the Company under the agreement are non-refundable. In 2006, the Company revised its estimate of remaining total costs to be incurred under the collaboration agreement with MedImmune. The change in estimate resulted in an increase in revenue recognized of approximately \$2.0 million in 2006.

In connection with this agreement, the Company received \$12.5 million in upfront license fees and research funding, which was paid in two installments: \$10.0 million in late 2003 and \$2.5 million in early 2004. In 2005, the Company reached a specified milestone and received \$1.25 million from MedImmune. In the event that specified research and development and commercialization milestones are achieved, MedImmune will be obligated to make further payments to the Company. In addition, the Company received approximately \$125,000, \$1.0 million and \$1.5 million in research funding from MedImmune in each of the years ended December 31, 2007, 2006 and 2005, respectively.

Revenue under this arrangement was being recognized under a proportional performance model. During 2007, 2006 and 2005, the Company recognized revenue of approximately \$400,000, \$6.3 million and \$5.7 million, respectively. In 2007, the Company completed the research term of its agreement with MedImmune resulting in the full recognition of all revenue that had been previously deferred from the prior year. As of December 31, 2006, the Company had deferred revenue of approximately \$275,000 related to this agreement. The deferred revenue consisted of a portion of the up-front payments, milestone and research funding received in advance of revenue recognized under the agreement.

***Beckman Coulter***

In January 2005, the Company entered into a license agreement with Beckman Coulter, under which the Company granted to Beckman Coulter and its affiliates an exclusive worldwide license to patent rights and know-how controlled by the Company relating to the use of high mobility group box protein 1 ( HMGB1 ) and its antibodies in diagnostics, to evaluate, develop, make, use and sell a kit or assemblage of reagents for measuring HMGB1 that utilizes one or

more monoclonal antibodies to HMGB1 developed by or on behalf of the Company.

In consideration for the license, Beckman Coulter paid the Company a product evaluation license fee of \$250,000 in February 2005. Beckman Coulter also agreed to pay the Company additional license fees of \$400,000 upon the occurrence of the exercise by Beckman Coulter of its option to undertake formal product development and \$450,000 upon the achievement of the first commercial sale of a licensed product. Beckman

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Coulter also agreed to pay the Company royalties based on net sales of licensed products by Beckman Coulter and its affiliates. Beckman Coulter has the right to grant sublicenses under the license subject to the Company's written consent, which the Company has agreed not to unreasonably withhold. Beckman Coulter agreed to pay the Company a percentage of any license fees, milestone payments or royalties actually received by Beckman Coulter from its sublicensees. Beckman Coulter exercised its development option under the license agreement in December 2006 and paid the Company \$400,000 in January 2007. This amount was recognized as revenue under collaboration and license agreements in 2007. The \$400,000 was included in amounts due under collaboration agreements and revenue deferred under collaboration agreements at December 31, 2006. No amount was due under the agreement as of December 31, 2007.

***Innovative Metabolics, Inc.***

In January 2007, the Company entered into an exclusive license agreement with IMI under which the Company licensed to IMI patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. In May 2007, under the agreement with IMI, the Company received an initial license fee of \$500,000 in cash and IMI junior preferred stock valued at \$500,000 in connection with IMI's first financing. However, under its license agreement with The Feinstein Institute, the Company was obligated to pay The Feinstein Institute \$100,000 of this cash payment and IMI junior preferred stock valued at \$100,000. The Company included in revenue under collaboration and license agreements in 2007 the \$1.0 million total license fee that the Company received from IMI and included the payments of \$100,000 in cash and IMI junior preferred stock valued at \$100,000 that the Company made to The Feinstein Institute in research and development expenses. These amounts were recorded in the second quarter of 2007. Under the license agreement, IMI also has agreed to pay the Company \$1.0 million, excluding a \$200,000 payment that the Company would be obligated to pay The Feinstein Institute, upon full regulatory approval of a licensed product by the FDA or a foreign counterpart agency and royalties based on a net sales of licensed products and methods by IMI and its affiliates.

On March 14, 2008, the Company sold 400,000 shares of junior preferred stock issued to it by IMI in May 2007 in connection with IMI's first financing for an aggregate purchase price of \$400,000. The Company sold these shares of junior preferred stock to two investors which had previously participated in IMI's first financing. The purchase price is subject to adjustments if these investors sell or receive consideration for these shares of junior preferred stock pursuant to an acquisition of IMI prior to February 1, 2009 at a price per share greater than they paid the Company.

**(4) Inventory**

Inventory consisted of the following at December 31 (in thousands):

	<b>2007</b>	<b>2006</b>
Raw material	\$ 2,587	\$ 3,662
Work-in-process	3,062	83
Finished goods	766	422
Total	6,415	4,167



Less reserve	(816)	(119)
Inventory	\$ 5,599	\$ 4,048

F-18

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(5) Fixed Assets**

Fixed assets consisted of the following at December 31 (in thousands):

	<b>2007</b>	<b>2006</b>
Laboratory equipment	\$ 759	\$ 1,219
Computer and office equipment	685	689
Equipment-in-process	2	686
Furniture and fixtures	332	488
Software	464	484
Leasehold improvements	186	280
Assets held under capital lease	32	32
 Total	 2,460	 3,878
Less accumulated depreciation and amortization	(1,309)	(1,457)
 Fixed assets net	 \$ 1,151	 \$ 2,421

In 2005, the Company entered into a capital lease arrangement primarily for computers for its sales force totaling \$125,000. Assets acquired under capital lease agreements were initially recorded at the present value of the future minimum rental payments using interest rates appropriate at the inception of the lease. Property and equipment subject to capital lease agreements are amortized over the shorter of the life of the lease or the estimated useful life of the asset. At December 31, 2007 the Company's net book value related to its capital leases was \$1,000. Included in laboratory equipment are assets held for sale valued at \$167,000.

Depreciation and amortization expense on fixed assets for the years ended December 31, 2007, 2006 and 2005 was approximately \$531,000, \$939,000 and \$800,000, respectively. In 2006, the Company adjusted accumulated depreciation by approximately \$750,000 related to assets with a net book value of \$872,000 that the Company deemed impaired as part of its 2006 restructuring and assets retired during the year ended December 31, 2006. In addition in 2007, the Company accelerated depreciation and recorded an impairment charge on fixed assets of \$275,000 as a result of its 2007 facility abandonment.

**(6) Accrued Expenses**

Accrued expenses consisted of the following at December 31 (in thousands):

	<b>2007</b>	<b>2006</b>
Research and development contracts	\$ 973	\$ 363
Product returns	873	

Marketing and promotion costs	784	
Professional fees	624	365
Other	1,849	1,348
Total	\$ 5,103	\$ 2,076

**(7) Long-Term Debt**

In June 2002, the Company entered into a loan and security agreement (the Agreement ) with a lender that allowed the Company to borrow up to \$2.25 million to finance the purchase of equipment and \$750,000 to finance leasehold improvements through June 30, 2003.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In June 2004, the Company entered into a modification to the Agreement. The modification gave the Company the ability to borrow up to an additional \$3.0 million under the Agreement from July 1, 2004 to December 31, 2004. In 2005, the Company had additional borrowing capacity up to an amount equal to the lesser of (i) \$3.0 million minus the principal amount of advances made in 2004 or (ii) \$1.3 million. During 2005, the Company borrowed \$1.3 million under the modified Agreement. No advances were made in 2006 under the modified Agreement. At December 31, 2007, the Company had no borrowing capacity available under the modified Agreement or any other credit agreement. Advances made under the modified Agreement accrue interest at a rate equal to the prime rate plus 2% per year and are required to be repaid in equal monthly installments of principal plus interest accrued through the date of repayment. The repayment terms for advances made under this modification are between 36 and 42 months. In connection with the original Agreement, the Company granted the lender a first priority security interest in substantially all of the Company's assets, excluding intellectual property, to secure the Company's obligations under the Agreement.

As of December 31, 2007, there was \$369,000 in debt outstanding under the modified Agreement. The outstanding borrowings bear interest at a rate of approximately 9.3%.

The repayments of principal and interest are scheduled to be made as follows (in thousands):

	<b>Principal</b>	<b>Interest</b>	<b>Total</b>
2008	\$ 369	\$ 4	\$ 373
	\$ 369	\$ 4	\$ 373

In January 2008, all outstanding debt under the modified Agreement was paid in full.

**(8) Stockholders Equity*****2006 Registered Offering***

In October 2006, the Company sold 7,455,731 shares of its common stock at a price of \$2.68 per share, together with warrants to purchase an additional 3,727,865 shares of common stock, for a total purchase price of \$20.0 million. The sales were made in a registered offering conducted as a direct placement through a placement agent. The net proceeds from the offering were approximately \$18.5 million, after deducting placement agents fees and other offering costs of approximately \$1.5 million.

The warrants issued in connection with the offering have an exercise price per share of \$2.62 per share, with a five-year life and are fully vested and exercisable from October 26, 2006. The warrants have been included in equity at their fair value of \$5.7 million. The fair value of the warrants was determined using the Black-Scholes model with the following assumptions: dividend yield of 0%; estimated volatility of 64%; risk-free interest rate of 4.51% and a contractual life of five years. As of December 31, 2007, none of these warrants had been exercised.

***2005 Private Placement***

In June 2005, the Company sold 9,945,261 shares of its common stock at a price of \$5.48 per share, together with warrants to purchase an additional 3,480,842 shares of common stock, for a total purchase price of \$54.5 million in a private placement. The sales were made to institutional and other accredited investors. The net proceeds from the private placement were approximately \$51.4 million, after deducting placement agents fees and other offering costs of approximately \$3.1 million.

In connection with this private placement, the Company issued and sold an aggregate of 5,200,732 shares of common stock and warrants to purchase 1,820,257 shares of common stock to existing stockholders and affiliated entities associated with four members of the Company's Board of Directors. These holders paid an

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

aggregate consideration of \$28.5 million and participated on the same terms as the other purchasers in the private placement.

The warrants issued in connection with the private placement have an exercise price per share of \$6.58, with a five-year life and are fully vested and exercisable from June 20, 2005. The warrants may also be exercised on a cashless basis at the option of the warrant holder. The warrants have been included in permanent equity at their fair value of \$9.2 million. The fair value of the warrants was determined using the Black-Scholes model with the following assumptions: dividend yield of 0%; estimated volatility of 58%; risk-free interest rate of 3.65% and a contractual life of five years. As of December 31, 2007, none of these warrants had been exercised.

***Authorized Capital***

As of December 31, 2007, the authorized capital stock of the Company consists of 90,000,000 shares of voting common stock ( common stock ) with a par value of \$0.001 per share, and 5,000,000 shares of undesignated preferred stock ( preferred stock ) with a par value of \$0.001 per share. The common stock holders are entitled to one vote per share. The rights and preferences of the preferred stock may be established from time to time by the Company's Board of Directors.

***Restricted Common Stock Issuances to Non-Employees***

The Company has made several grants of restricted common stock to non-employees since its inception. Many of these restrictions have lapsed, and therefore, no longer require periodic remeasurement in our financial statements.

During 2001, the Company issued 27,259 shares of common stock subject to restrictions and vesting, as partial consideration for a sponsored research and licensing agreement with The Feinstein Institute (see Note 12). 25% of the shares vested immediately, 25% vested in 2001, 25% vested on July 1, 2006, and the remaining 25%, or 6,815 shares vested on July 1, 2007.

In 2007, the Company issued 26,700 shares of restricted stock to a consultant. The fair value at the date of grant was \$24,000. The Company is recording stock-based compensation ratably over the 24 month vesting period. The Company did not issue restricted stock to non-employees in 2006 or 2005.

Compensation to date associated with the restricted stock issued to non-employees has been measured as the difference between the fair value of the shares and the amount paid by the holder. Final measurement occurs when performance is complete, which is assumed to be when the restrictions lapse. The Company recorded approximately \$11,000 in stock-based compensation expense for the year ended December 31, 2007 related to these shares. In addition, the Company reduced by approximately \$62,000 and \$137,000 its previously recorded deferred stock-based compensation for years ended December 31, 2006 and 2005, respectively, related to these shares. These amounts are included in operating expenses in the accompanying consolidated statement of operations.

The Company has reserved 12,229,610 shares as of December 31, 2007 for options outstanding under the Company's 2004 Stock Incentive Plan and outstanding warrants.

**(9) Equity Incentive Plans**

***2006 Stock Purchase Plan***

On February 23, 2006, the Company's Board of Directors adopted, and on April 25, 2006, the Company's stockholders approved, the Company's 2006 Employee Stock Purchase Plan (the "2006 Stock Purchase Plan") for the issuance of up to 400,000 shares of the Company's common stock to participating employees. The

F-21

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

2006 Stock Purchase Plan is implemented by offering periods with a duration of six months. Offerings begin each June 1 and December 1, or the first business day thereafter, and first commenced June 1, 2006.

On the first day of an offering period, the Company grants to each eligible employee who has elected to participate in this plan a purchase right for shares of common stock. The employee may authorize up to 15% of his or her compensation to be deducted during the offering period. On the last business day of the offering period, the employee will be deemed to have exercised the purchase right, at the applicable purchase price per share, to the extent of accumulated payroll deductions. The purchase price per share under this plan is 85% of the lesser of the closing price per share of the common stock on the NASDAQ Global Market on the first day of the offering period or the last business day of the offering period. The 2006 Stock Purchase Plan may be terminated at any time by the Company's Board of Directors.

For the years ended December 31, 2007 and 2006, the Company issued 40,149 and 13,360 shares, respectively, of the Company's common stock to participating employees.

***2004 Stock Incentive Plan***

On April 7, 2004, the Company's Board of Directors adopted, and on May 6, 2004 the Company's stockholders approved, the 2004 Stock Incentive Plan (the "2004 Stock Plan") for the issuance of up to 3,680,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, and restricted common stock to key employees, directors, consultants, and vendors of the Company and its affiliates.

On March 15, 2005, the Company's Board of Directors adopted, and on June 17, 2005 the Company's stockholders approved, an amendment to the 2004 Stock Plan to increase the total number of shares available by 860,000.

On January 1, 2006, the Company's Board of Directors amended the 2004 Stock Plan to increase the total number of shares authorized for issuance by an additional 1,333,333, bringing the total authorized under the 2004 Stock Plan to 5,873,333 shares. At December 31, 2007, the Company had 1,045,486 shares of common stock available for award under the 2004 Stock Plan.

The exercise price of stock options is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. Options generally become exercisable over a period of four years from the date of grant, and expire 10 years after the grant date.

***2003 Stock Incentive Plan***

On September 29, 2003, the Company's Board of Directors and stockholders adopted the 2003 Stock Incentive Plan (the "2003 Stock Plan") for the issuance of incentive stock options, nonqualified stock options, and restricted common stock to key employees, directors, consultants, and vendors of the Company and its affiliates. On December 9, 2003, the Company's Board of Directors amended the 2003 Stock Plan to increase the total number of shares available to 1,590,666 from 524,000, plus the 284,739 shares available from the 2000 Equity Plan. On June 2, 2004, in connection with the adoption of the 2004 Stock Plan, the Company transferred the 132,561 remaining shares of common stock available for award in the 2003 Stock Plan to the 2004 Stock Plan, subject to future adjustment based upon further



cancellations in the 2003 Stock Plan or the 2000 Equity Plan. Accordingly, there are no shares of common stock available for award under the 2003 Stock Plan at December 31, 2007.

Under the terms of the 2003 Stock Plan, the exercise price of incentive stock options granted was established by the Board of Directors. The vesting provisions for stock options and restricted stock were established by the Board of Directors.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****2000 Equity Incentive Plan***

On July 14, 2000, the Company's Board of Directors and Company stockholders adopted the 2000 Equity Incentive Plan (the "2000 Equity Plan") for the issuance of incentive stock options, nonqualified stock options, and restricted common stock to key employees, directors, consultants, and vendors of the Company and its affiliates. On October 24, 2002, the Company's Board of Directors amended the 2000 Equity Plan to increase the total number of shares available to 4,000,000 from 2,000,000. On September 29, 2003, in connection with the adoption of the 2003 Stock Plan, the Company transferred the 284,739 remaining shares of common stock available for award in the 2000 Equity Plan to the 2003 Stock Plan, subject to future adjustments. Accordingly, there are no shares of common stock available for award under the 2000 Equity Plan at December 31, 2007.

Under the terms of the 2000 Equity Plan, the exercise price of incentive stock options granted must not be less than the fair market value of the common stock on the date of grant, as determined by the Board of Directors. The exercise price of nonqualified stock options and the purchase price of restricted common stock may be less than the fair market value of the common stock on the date of grant, as determined by the Board of Directors, but in no case may the exercise price or purchase price be less than the statutory minimum. The vesting provisions for stock options and restricted stock were established by the Board of Directors.

The following table summarizes stock option activity under all of the plans:

		<b>Number of Shares</b>	<b>Weighted- Average Exercise Price</b>
Outstanding	January 1, 2005	4,500,270	\$ 4.23
Granted		2,025,900	6.70
Exercised		(96,235)	1.64
Cancelled		(229,829)	5.54
Outstanding	December 31, 2005	6,200,106	5.03
Granted		3,428,000	4.10
Exercised		(752,241)	0.82
Cancelled		(3,169,600)	5.81
Outstanding	December 31, 2006	5,706,265	4.60
Granted		1,011,800	2.12
Exercised		(247,386)	1.04
Cancelled		(1,449,776)	4.84
Outstanding	December 31, 2007	5,020,903	\$ 4.20
Vested or expected to vest	December 31, 2007	4,387,001	\$ 4.25

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Exercisable	December 31, 2005	1,809,920	\$	3.42
Exercisable	December 31, 2006	2,047,280	\$	4.91
Exercisable	December 31, 2007	2,379,213	\$	4.85

F-23

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## CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The options outstanding and exercisable at December 31, 2007 under the plans are as follows:

Exercise Price	Number of Options Outstanding	Outstanding Weighted- Average Contractual Life Outstanding (In Years)	Weighted- Average Exercise Price	Exercisable Options Exercisable	Weighted- Average Exercise Price
\$0.38-\$1.80	617,992	7.7	\$ 1.38	353,251	\$ 1.09
\$1.88	644,159	9.0	\$ 1.88	164,049	\$ 1.88
\$1.93-\$2.33	503,400	9.1	\$ 2.14	14,166	\$ 2.11
\$2.38-\$3.71	188,900	9.2	\$ 2.87	23,324	\$ 3.03
\$3.80	817,196	8.4	\$ 3.80	310,318	\$ 3.80
\$4.31-\$5.63	507,144	6.5	\$ 5.35	419,374	\$ 5.39
\$5.75-5.99	548,750	6.5	\$ 5.97	348,292	\$ 5.97
\$6.00-\$6.83	592,781	6.9	\$ 6.55	367,636	\$ 6.58
\$6.85-\$7.75	528,081	7.3	\$ 7.27	318,783	\$ 7.31
\$7.78-\$8.96	72,500	7.2	\$ 8.14	60,020	\$ 8.05
	5,020,903	7.8	\$ 4.20	2,379,213	\$ 4.85

The weighted-average fair value of stock option grants using the Black-Scholes option pricing model were \$1.43, \$2.58 and \$3.26 per share in 2007, 2006 and 2005, respectively.

The weighted average remaining contractual term and the aggregate intrinsic value for options outstanding at December 31, 2007 were 7.8 years and \$84,000, respectively. The weighted average remaining contractual term and the aggregate intrinsic value for options vested or expected to vest at December 31, 2007 were 7.7 years and \$84,000, respectively. The weighted average remaining contractual term and the aggregate intrinsic value for options exercisable at December 31, 2007 were 6.9 years and \$83,000, respectively. The total intrinsic value of the options exercised during the years ended December 31, 2007, 2006 and 2005 was approximately \$221,000, \$1.4 million and \$567,000, respectively.

During 2007, the Company issued 442,600 shares of restricted common stock to employees. These shares vest 50% on the sixth-month anniversary of the grant date and 50% on the second anniversary of the grant date. During 2006, the Company issued 556,100 shares of restricted common stock to employees. These shares vest 50% on the first anniversary of the grant date and 50% on the second anniversary of the grant date. In addition, under the restricted stock agreements granted in 2007 and 2006, 50% of all unvested restricted common stock vests upon a change-of-control event, as defined in the Company's 2004 Stock Incentive Plan. In August 2007, the Company's Board of Directors approved a share surrender plan in connection with the employee restricted stock vesting in November and December 2007. As a result, the Company allowed employees to surrender 67,929 shares in lieu of

their tax obligation. During 2007 the Company paid \$111,000 to various tax authorities on behalf of its employees who surrendered shares.

F-24

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## CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes the restricted stock activity for the years ended December 31:

	2007		2006		2005	
	Number of Shares	Weighted- Average Grant- Date Fair Value	Number of Shares	Weighted- Average Grant- Date Fair Value	Number of Shares	Weighted- Average Grant- Date Fair Value
Nonvested at beginning of year	556,100	\$ 2.00	40,803	\$ 0.38	103,613	\$ 0.38
Granted	442,600	1.86	556,100	2.00		
Vested	(240,100)	1.47	(38,536)	0.38	(62,810)	0.38
Forfeited	(149,350)	1.97	(2,267)	0.38		
Nonvested at end of year	609,250	\$ 1.90	556,100	\$ 2.00	40,803	\$ 0.38

In the years ended December 31, 2007, 2006 and 2005 the Company recorded stock-based compensation of \$3.9 million, \$7.2 million and \$2.1 million, respectively.

The following table summarizes deferred stock-based compensation activity for the years ended December 31 (in thousands):

	2007	2006	2005
Deferred Compensation Balance Beginning	\$ (99)	\$ (3,794)	\$ (6,101)
<i>Employees</i>			
Amortization of deferred stock-based compensation	61	500	1,757
Reversal of deferred stock-based compensation	3	2,686	221
<i>Non-employees</i>			
Amortization of deferred stock-based compensation			384
Deferred stock-based compensation	\$ (39)	(395)	(513)
Re-measure deferred stock-based compensation	74	904	458
Deferred Compensation Balance Ending	\$	\$ (99)	\$ (3,794)

Compensation expense for 2007 related to options and restricted stock issued to employees is included in the accompanying consolidated statement of operations as research and development, sales and marketing and general and administrative expense in the amounts of \$1.0 million, \$424,000 and \$2.5 million, respectively. Compensation expense for 2006 related to options issued to employees is included in the accompanying consolidated statement of

operations as research and development, sales and marketing, general and administrative and restructuring expense in the amounts of \$1.7 million, \$1.1 million, \$4.2 million and \$622,000, respectively. Compensation expense for 2005 related to these options is included in the accompanying consolidated statement of operations as research and development, sales and marketing and general and administrative expense in the amounts of \$489,000, \$119,000 and \$1.2 million, respectively.

During 2007, 2006 and 2005, all options issued to employees were granted at exercise prices equal to fair market value on the date of grant.

F-25

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes the Company's stock-based compensation for the years ended December 31 (in thousands):

	2007	2006	2005
Stock-based compensation			
<i>Employees</i>			
Stock-based compensation adoption of 123(R)	\$ 3,714	\$ 7,137	\$
Stock compensation Intrinsic value awards	61	500	1,757
<i>Non-employees</i>			
Stock-based compensation adoption of 123(R)	195		
Stock-based compensation (reversals)	(39)	(395)	384
Total	\$ 3,931	\$ 7,242	\$ 2,141

During 2007, 2006 and 2005, the Company granted 50,000, 230,000 and 161,000 options, respectively, to non-employees that are accounted for in accordance with SFAS No. 123(R) and the measurement guidance of EITF No. 96-18. The fair value of these awards was estimated using the Black-Scholes option-pricing methodology and was deemed to be \$69,000 for 2007, \$369,000 for 2006 and \$513,000 for 2005. The Company adjusted its compensation expense by approximately \$319,000 for the year ended December 31, 2006 and recorded compensation expense of approximately \$145,000 and \$520,000 related to these options for the years ended December 31, 2007, and 2005, respectively. Compensation expense in 2007 related to these options is included in the accompanying consolidated statement of operations as sales and marketing and general and administrative expense in the amounts of \$5,000 and \$154,000, respectively, offset by an adjustment of \$14,000 in research and development expense. The compensation adjustment in 2006 related to these options is included in the accompanying consolidated statement of operations as an adjustment of \$330,000 in research and development expense offset by stock-based compensation expense of \$11,000 in general and administrative expense. Compensation expense in 2005 related to these options is included in the accompanying consolidated statement of operations as research and development and general and administrative expense in the amounts of \$512,000 and \$8,000, respectively.

As of December 31, 2007, there was \$7.3 million of total unrecognized compensation expense (including the pre Form S-1 options) related to unvested share-based compensation awards granted under the Company's stock incentive plans, which is expected to be recognized over a weighted-average period of 1.2 years.

The Company anticipates recording additional stock-based compensation expense of \$3.4 million in 2008, \$2.7 million in 2009 and \$1.1 million thereafter relating to the amortization of unrecognized compensation expense as of December 31, 2007. These anticipated compensation expenses do not include any adjustment for new or additional options to purchase common stock granted to employees.

The Company entered into employment agreements with its officers. These agreements provide for, among other things, certain severance benefits and acceleration of vesting for stock options and restricted stock contingent upon future events such as a change-of-control of the Company. Because the terms in the employment agreements modified



certain provisions of each officer's existing stock awards, a new measurement date was created for the awards. If a change-of-control occurs, the Company would be required to record the intrinsic value of any options or restricted stock that vest on the date of a change-of-control. The intrinsic value is calculated as the difference between the fair value of common stock on the date of remeasurement and the exercise price of the underlying stock option or the purchase price of restricted stock. As of December 31, 2007, there were 1.8 million unvested stock options and restricted stock subject to the modification. If a change-of-control were to occur and all of these securities were to vest, \$3.6 million would be recorded as stock-based compensation expense.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(10) Employee Benefit Plan**

During 2003, the Company adopted a 401(k) profit sharing plan (the 401(k) Plan ) covering all employees of the Company who meet certain eligibility requirements. Under the terms of the 401(k) Plan, the employees may elect to make tax-deferred contributions through payroll deductions within statutory and plan limits and the Company may elect to make matching or voluntary contributions. During 2005, the Company matched 100% of employee contributions up to a maximum of \$1,000 per employee resulting in expense of \$122,000. In November 2005, the Company's Board of Directors amended the 401(k) Plan, effective January 1, 2006, to provide a matching contribution to each participant of 50% of the participant's elective deferrals for a plan year up to 6% of the participant's salary up to a maximum of \$3,000, which resulted in expense of \$177,000 and \$303,000 in 2007 and 2006, respectively.

**(11) Income Taxes**

In July 2006, the FASB issued FIN 48, which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FAS 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

The adoption of FIN 48 did not impact the Company's financial condition, results of operations, or cash flows. At December 31, 2007, the Company had net deferred tax assets of \$70.5 million. Because of the Company's limited operating history and the uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, management has provided a 100% valuation allowance against the Company's net deferred tax assets. As a result, the Company increased its valuation allowance by \$13.4 million for the year ended December 31, 2007. This change was primarily the result of the increase in the Company's net operating loss carryforward.

Net operating losses and credits are subject to review and possible adjustments by the Internal Revenue Service and may be limited in the event of certain cumulative changes in ownership. The Tax Reform Act of 1986 contains provisions that may limit the utilization of net operating loss carryforwards and credits available to be used in any given year in the event of significant changes in ownership interest, as defined. The Company has recorded a full valuation allowance as an offset against these otherwise recognizable net deferred tax assets due to the uncertainty surrounding the timing of the realization of the tax benefit. In the event that the Company determines in the future that it will be able to realize all or a portion of its net deferred tax benefit, an adjustment to deferred tax valuation allowance would increase earnings in the period in which such a determination is made.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company's deferred tax accounts consisted of the following at December 31 (in thousands):

	<b>2007</b>	<b>2006</b>
Deferred tax assets:		
Net operating loss carryforward	\$ 65,007	\$ 52,396
Research and experimentation credits	1,898	2,110
Depreciation and amortization	1,602	673
Stock-based compensation	1,513	822
Deferred revenue		756
Other	480	385
 Total	 70,500	 57,142
Less valuation allowance	(70,500)	(57,142)
 Total	 \$	 \$

A portion of the net operating loss carry forwards as of December 31, 2007 include amounts related to stock option deductions. Under SFAS 123(R), any excess tax benefits from stock-based compensation are only realized when income taxes payable is reduced, with the corresponding credit posted to additional paid-in capital.

As of December 31, 2007, the Company had federal tax net operating loss carryforwards of approximately \$163 million which expire beginning in 2021 and had state tax net operating loss carryforwards of approximately \$154 million which expire beginning in 2008. The Company also has research and experimentation credit carryforwards of approximately \$1.9 million, which begin to expire in 2021. The Company is subject to taxation by the IRS and by The Commonwealth of Massachusetts. All years are currently open for examination for federal return purposes and for years 2002 through 2007 for The Commonwealth of Massachusetts.

As of December 31, 2007, the total amount of net unrecognized tax benefit was \$202,000, which has been recorded as a reduction to the deferred tax asset with an offsetting adjustment to the Company's valuation allowance. Included in the balance of unrecognized tax benefits at December 31, 2007, are \$179,000 of tax benefits that, if recognized, would affect the effective tax rate.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties as income tax expense. Related to the uncertain tax benefits noted above, the Company had no accrual for interest or penalties on the Company's balance sheets at December 31, 2006 and at December 31, 2007, and has not recognized interest and/or penalties in the statement of operations for the year ended December 31, 2007.

**(12) Research and License Agreements**

The following is a summary of the Company's significant research and license agreements:

*Abbott*

In December 2003, the Company entered into an agreement to in-license the controlled-release formulation and the injectable formulation of zileuton from Abbott Laboratories ( Abbott ). The Company has the right to commercialize this product for all clinical indications except for research, diagnostics, therapeutics and services to humans under age seven and for cardiovascular and vascular devices. The Company is obligated to make milestone payments to Abbott for successful completion of the technology transfer, filing and approval of the product in the United States and commercialization of the product. In addition, the Company will make royalty payments to Abbott based upon sales of the product. The agreement may be terminated by either party

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

for cause. The Company may also terminate the agreement at any time upon 60- days notice to Abbott and payment of a termination fee. In May 2007, the Company received approval by the FDA of the new drug application ( NDA ) for ZYFLO CR. As a result of the FDA approval, the Company paid \$2.5 million under this agreement in June 2007 and accrued an additional \$2.8 million of which \$1.5 million will be due on each of the first and second anniversary, respectively, of the FDA s approval of ZYFLO CR. The amounts due on the first and second anniversary of the FDA s approval were accrued at the present value of the total \$3.0 million owed, and the accretion of the discount is included in interest expense. The \$2.5 million paid and the \$2.8 million accrued as a result of the FDA s approval of ZYFLO CR were included in the Company s research and development expenses in 2007. For the year ended December 31, 2007, the Company recorded interest expense of \$78,000 related to the accretion of the discount. During 2004, the Company paid milestone payments of \$2.5 million to Abbott under this agreement. No payments were made during 2005 under the agreement. During 2006, the Company paid milestone payments of \$1.5 million to Abbott related to the filing of the Company s NDA for ZYFLO CR.

In March 2004, the Company entered into an agreement to in-license an immediate-release formulation of zileuton from Abbott. The Company agreed to pay a license fee of \$500,000, a milestone payment and royalties to Abbott based upon sales of the product. The agreement may be terminated by either party for cause. The Company may also terminate the agreement at any time upon 60-days notice to Abbott. During 2004, the Company paid the \$500,000 license fee, and did not pay any milestones under this agreement. During 2005, the Company paid milestone payments of \$750,000 to Abbott related to the filing of the Company s supplemental new drug application ( sNDA ) for the immediate-release formulation of zileuton. No payments were made during 2006 and 2007 under the agreement.

***SkyePharma***

In December 2003, the Company entered into an agreement with a subsidiary of SkyePharma PLC ( SkyePharma ), to in-license the controlled-release technology relating to zileuton. The Company is required to make milestone payments to SkyePharma for successful completion of the technology transfer, filing and approval of the product in the United States and commercialization of the product. In addition, the Company will make royalty payments to SkyePharma based upon sales of the product. The agreement may be terminated by either party for cause. As a result of the FDA s May 2007 approval of the Company s NDA for ZYFLO CR, the Company paid \$625,000 under this agreement in June 2007 and accrued an additional \$699,000 of which \$375,000 will be due on each of the first and second anniversary, respectively, of the FDA s approval. The amounts due on the first and second anniversary of the FDA s approval were accrued at the present value of the total \$750,000 owed, and the accretion of the discount is included in interest expense. The \$625,000 paid and the \$699,000 accrued as a result of the FDA s approval were included in the Company s research and development expenses in 2007. For the year ended December 31, 2007, the Company recorded interest expense of \$20,000 related to the accretion of the discount. No payments were made to SkyePharma during 2004 under the agreement. The Company paid \$375,000 and \$1.3 million in 2006 and 2005, respectively, to SkyePharma under this agreement.

***The Feinstein Institute***

In July 2001, the Company entered into a license agreement with The Feinstein Institute whereby the Company has agreed to utilize certain of The Feinstein Institute s technology in its research effort in connection with one of its research targets, HMGB1. The Company paid and expensed \$100,000 to The Feinstein Institute for the license and may be required to pay an additional \$412,500 if certain research milestones are achieved. As of December 31, 2007,

none of these milestones had been achieved. In addition, the Company is obligated to pay royalties to The Feinstein Institute based on product sales. In the event of no product sales, the Company will be required to pay minimum annual royalties of \$15,000 in years 2008 through 2011 and \$75,000 in years 2012 through the expiration of the patent in 2023. The Company paid the

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

minimum annual royalty of \$15,000 in 2007. The Company also agreed to pay all patent maintenance costs incurred after July 1, 2001 and to reimburse The Feinstein Institute up to \$50,000 in patent costs incurred prior to July 1, 2001.

In December 2003, this agreement was amended to redefine the sublicense fees payable to The Feinstein Institute. In connection with the amendment, the Company agreed to issue 66,666 shares of common stock having a value of \$485,000 to The Feinstein Institute (see Note 8). As a result of the collaboration agreement with MedImmune (see Note 3), the Company incurred an obligation to pay a sublicense fee to The Feinstein Institute. The Company paid sublicense fees in the amounts of \$100,000, \$250,000 and \$0 in 2007, 2006, and 2005, respectively, to The Feinstein Institute. At December 31, 2007 and 2006, \$13,000 and \$100,000, respectively, was included in accrued liabilities related to the agreement. As a result of our collaboration agreement with Beckman Coulter (see Note 3), the Company paid a sublicense fee of \$80,000 to The Feinstein Institute in 2007.

Also in July 2001, the Company entered into a sponsored research and license agreement with The Feinstein Institute whereby the Company committed to \$400,000 of research funding over a period of two years in connection with efforts to identify HMGB1 inhibitors. In July 2003, the Company amended the Agreement to provide for the Company's contribution of an additional \$600,000 of research funding. During 2006 and 2005, the Company contributed a total of \$100,000 and \$200,000, respectively, in research funding. The Company contributed no research funding in 2007. In connection with obtaining certain licenses from The Feinstein Institute, the Company issued 27,259 shares of its common stock (see Note 8), subject to repurchase restrictions, and may pay up to an additional \$300,000 if certain research milestones are achieved. As of December 31, 2007, none of these milestones had been achieved. In addition, the Company is obligated to pay royalties to The Feinstein Institute based on product sales.

In January 2003, the Company entered into a second sponsored research and license agreement with The Feinstein Institute whereby the Company committed to \$600,000 of research funding in the field of alpha-7 cholinergic anti-inflammatory technology over a period of three years and paid a \$175,000 license fee during 2003. In January 2007, the agreement was amended resulting in the Company committing an additional \$120,000 of research funding in 2007. During 2007, 2006, and 2005, the Company contributed a total of \$120,000, \$150,000, and \$250,000, respectively, in research funding. The Company may be required to pay an additional \$1.5 million in cash and common stock if certain milestones are achieved as well as royalty payments based on product sales. In the event of no product sales, the Company will be required to pay minimum annual royalties of \$100,000 in 2008, which will increase by \$50,000 annually to a maximum of \$400,000 in 2014 through the expiration of the patent in 2023. As of December 31, 2007, none of these milestones had been achieved.

***Patheon Pharmaceuticals Inc.***

In June 2005, the Company entered into a commercial manufacturing agreement with Patheon Pharmaceuticals Inc. ( Patheon ) for the manufacture of commercial supplies of ZYFLO immediate-release tablets. The Company had previously contracted with Patheon for the manufacture of ZYFLO for clinical trials and regulatory review. Under the agreement, the Company is responsible for supplying the active pharmaceutical ingredient for ZYFLO to Patheon and Patheon is responsible for manufacturing the ZYFLO immediate-release tablets and conducting stability testing. The Company has agreed to purchase at least 50% of its commercial supplies of ZYFLO immediate-release tablets for sale in the United States from Patheon each year for the term of the agreement.

The commercial manufacturing agreement has an initial term of three years beginning on the date that commercial manufacturing of the ZYFLO immediate-release tablets commences and will automatically continue for successive one-year periods thereafter, unless the Company provides Patheon 12-months prior written notice of termination or Patheon provides the Company 18-months prior written notice of termination.



**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

If the Company provides six-months advance notice that it intends to discontinue commercializing ZYFLO, the Company will not be required to purchase any additional quantities of ZYFLO immediate-release tablets, provided that the Company pays Patheon for a portion of specified fees and expenses associated with orders previously placed by the Company.

***Shasun Pharma Solutions Ltd.***

In February 2005, the Company entered into an agreement with Rhodia Pharma Solutions Ltd ( Rhodia ) for the manufacture of commercial supplies of the zileuton active pharmaceutical ingredient ( API ). The Company had previously contracted with Rhodia to establish and validate a manufacturing process for the zileuton API and to manufacture supplies of the zileuton API sufficient for the Company s clinical trials. Under the new commercial supply agreement, Rhodia has agreed to complete its validation process at sites operated by Rhodia and to manufacture the Company s required commercial supplies of the zileuton API, subject to specified limitations, through December 31, 2009. In June 2006, Rhodia SA, the parent company of Rhodia, sold the European assets of its pharmaceutical custom synthesis business to Shasun Chemicals and Drugs Ltd. As part of this transaction, Rhodia SA assigned the Company s contract with Rhodia to Shasun.

The agreement will automatically extend for successive one-year periods after December 31, 2009, unless Shasun provides the Company with 18-months prior written notice of cancellation. The Company has the right to terminate the agreement upon 12-months prior written notice for any reason, provided that the Company may not cancel prior to January 1, 2008 for the purpose of retaining any other company to act as its exclusive supplier of the API.

Under this agreement, the Company committed to purchase a minimum amount of API in the fourth quarter of 2006, the first quarter of 2007 and in the first quarter of 2008. In addition, we have agreed to purchase certain quantities in 2008 and 2009 with a portion subject to the right of cancellation, with a termination fee. The API purchased from Shasun currently has a shelf-life of 36 months and a retest schedule every 24 months. The Company evaluates the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, the Company is required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. While the purchase commitment for API from Shasun exceeds the Company s current forecasted demand in 2008, the Company expects that any excess API purchased in 2007 under its agreement with Shasun will be used in commercial production batches in 2008 and 2009 and sold before it requires retesting. Therefore no reserve for this purchase commitment has been recorded as of December 31, 2007.

Unless otherwise noted all milestone and other payments are included in research and development.

**(13) Commitments and Contingencies**

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. For all periods presented, the Company is not a party to any pending material litigation or other material legal proceedings.

***Lease Obligations***

In the third quarter of 2007, the Company ceased its in-house research activities to focus on the clinical development and commercialization aspects of its business. The Company recorded a liability of \$360,000 related to a portion of the remaining obligations under its then operating lease that would expire in March 2009 at its facility in Lexington, Massachusetts that the Company ceased to use. The liability recorded was reduced by an estimated sublease rental income that the Company estimated could be reasonably obtained for the unused portion of the facility. In December 2007, the Company adjusted this estimated sublease income to

F-31

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

reflect the negotiated termination of the Company's operating lease and the Company's sublease for the 11,298 square feet the Company currently occupies. This adjustment resulted in a \$140,000 reduction to the abandonment charges. The Company recorded the abandonment charges in the third and fourth quarter of 2007 in its research and development expenses. As of December 31, 2007, the remaining obligation under the operating lease was \$214,000, which is included in accrued expenses.

On January 16, 2008, the Company entered into a sublease with Microbia. The sublease was entered into in connection with the Company's negotiated termination of its lease, dated as of November 18, 2003, between the Company and ARE and the negotiation of a new lease between ARE and Microbia for the same premises. Pursuant to the terms of the sublease, the Company is subleasing from Microbia a portion of the current premises at 60 Westview Street, Lexington, Massachusetts totaling approximately 11,298 square feet effective March 1, 2008. The sublease has an initial term of 12 months and the Company has the right to extend this initial term by an additional six months by giving Microbia written notice of its intention to do so at least 120 days before the expiration of the initial term. The sublease provides for rent of \$372,834 per year, payable in equal monthly installments of \$31,069.50, and a cash security deposit of \$40,000. In addition, the Company agreed to sell to Microbia specified laboratory equipment and furniture located at 60 Westview Street.

At December 31, 2007, the Company's then existing facility lease contained a rent escalation clause that requires the Company to pay additional rental amounts in the later years of the lease term. Rent expense for this lease is recognized on a straight-line basis over the minimum lease term. As such, the Company has recorded a liability for rent expense in excess of payments made-to-date. As of December 31, 2007, this liability totaled \$48,000. As a result of the termination of its existing lease, the Company will record the rent expense in excess of payments made to date ratably over the remaining two months of the existing lease.

In addition to its facility, the Company also leases vehicles and certain computer equipment under operating leases. Rent expense under its operating leases for the years ended December 31, 2007, 2006 and 2005 was \$1.2 million, \$1.8 million and \$1.6 million, respectively. In addition, in 2005, the Company entered into a capital lease arrangement primarily for computers for its sales force totaling \$125,000.

The minimum aggregate future obligations under non-cancelable lease obligations as of December 31, 2007 are as follows (in thousands):

<b>Year Ending</b>	<b>Operating Leases</b>	<b>Capital Leases</b>
2008	668	5
2009	62	
Total minimum lease payments	\$ 730	\$ 5
Less amount representing interest		(0)
Present value of future minimum lease payments		5
		651

Less current portion	(5)
Long-term portion	\$

***Founders Consulting Agreements***

In January 2001, as amended in January 2003, each of the Company's three founders, one of whom was a member of the Company's Board of Directors, entered into a separate consulting agreement with the Company in which they contracted to provide consulting services to the Company. In January 2008, one of the agreements was extended through December 31, 2009. For the years ended December 31, 2007, 2006 and 2005, amounts paid under these agreements totaled \$36,000, \$320,000 and \$313,000, respectively.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company has entered into various agreements with third parties and certain related parties in connection with the research and development activities of its existing product candidates as well as discovery efforts on potential new product candidates. These agreements include costs for research and development and license agreements that represent the Company's fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These agreements include costs related to manufacturing, clinical trials and preclinical studies performed by third parties. The estimated amount that may be incurred in the future under these agreements totals approximately \$10.1 million as of December 31, 2007. The amount and timing of these commitments may change, as they are largely dependent on the rate of enrollment in and timing of the development of the Company's product candidates. Some of these agreements have been described in more detail in Note 12.

***Consulting Agreement with Director***

On October 25, 2006, the Company entered into a consulting agreement with a former member of its Board of Directors, under which the director agreed to provide the Company services related to commercial sales, marketing and business development initiatives and other such related projects. Under the consulting agreement, the Company agreed to pay \$1,800 per day and granted the director an option to purchase 200,000 shares of common stock under the 2004 Stock Plan. This option had an exercise price of \$2.63 per share and would vest in 36 equal monthly installments commencing on November 25, 2006. In addition, 50% of the then unvested options would vest upon a change-of-control or specified transactions as set forth in the consulting agreement. The fair value of these stock options on the date of grant using the Black-Scholes valuation model was \$330,000. The fair value of the stock option was expensed over the vesting period. The Company periodically remeasured the fair value of the unvested portion of the stock option, resulting in charges or credits to operations. During 2007 and 2006, the Company recorded \$141,000 and \$13,000, respectively, in stock-based compensation expense related to this option grant. The consulting agreement had a term of 12 months and automatically renewed on a month-to-month basis. The Company terminated the consulting agreement on June 22, 2007. The director's option to exercise his vested shares of common stock granted under the agreement expired on September 30, 2007 with no options being exercised. Through December 31, 2007 and 2006 the Company paid \$14,000 and \$65,000, respectively, for consulting performed under the agreement.

**(14) DEY Co-Promotion and Marketing Services Agreements**

On March 13, 2007, the Company entered into an agreement with DEY, under which the Company and DEY agreed to jointly promote ZYFLO and ZYFLO CR. Under the co-promotion and marketing services agreement, the Company granted DEY an exclusive right and license to promote and detail ZYFLO and ZYFLO CR in the United States, together with the Company.

Under the co-promotion agreement, DEY paid the Company a non-refundable upfront payment of \$3.0 million in March 2007, a milestone payment of \$4.0 million in June 2007 following approval by the FDA of the NDA for ZYFLO CR in May 2007 and a milestone payment of \$5.0 million in December 2007 following the commercial launch of ZYFLO CR. Under the co-promotion agreement, the Company will pay DEY a commission on quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, in excess of \$1.95 million. From the date DEY begins detailing ZYFLO through the commercial launch of ZYFLO CR, the commission rate was 70%, following the commercial launch of ZYFLO CR in September 2007 through December 31, 2010, the commission rate is 35% and from January 1, 2011 through December 31, 2013, the commission rate is 20%. The co-promotion agreement expires on December 31, 2013 and may be extended upon mutual agreement by the parties.

The Company has deferred the \$12.0 million in aggregate payments received to date and is amortizing these payments over the term of the agreement. The amortization of the upfront and milestone payments will be

F-33

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

offset by the co-promotion fees paid to DEY for promoting ZYFLO and ZYFLO CR. The Company records all ZYFLO and ZYFLO CR sales generated by the combined sales force and records any co-promotion fees paid to DEY and the amortization of the upfront and milestone payments as sales and marketing expenses. For the year ended December 31, 2007, approximately \$567,000 was amortized from the deferred co-promotion fees representing the amount earned by DEY during the periods.

On June 25, 2007, the Company entered into a definitive agreement with DEY to jointly promote DEY's product PERFOROMIST™ (formoterol fumarate) Inhalation Solution ( PERFOROMIST ), for the treatment of chronic obstructive pulmonary disease, or COPD. In October 2007, the Company announced that it commercially launched PERFOROMIST with DEY. Under the agreement, DEY agreed to pay the Company a commission on retail sales of PERFOROMIST. The agreement has a term expiring on December 31, 2013, which may be extended upon mutual agreement by the parties.

**(15) Restructurings Charges**

In May 2006, the Company recorded charges of \$499,000 for a restructuring of its operations that was intended to better align costs with revenue and operating expectations. The restructuring charges included \$95,000 in general and administrative expense, \$231,000 in research and development expense and \$173,000 in sales and marketing expense.

In connection with the May 2006 restructuring plan, the Company terminated 27 employees, or approximately 16% of the Company's workforce at the time, resulting in severance benefits of \$383,000, which were accrued in May 2006. As a result of terminating these employees, the Company recorded automobile lease termination fees of \$54,000, outplacement service fees of \$39,000 and an impairment charge of \$23,000 for computer equipment for which the future use was currently uncertain. At December 31, 2006, the Company had \$9,000 remaining in accrued expenses related to the May restructuring. At December 31, 2007, there no remaining accrued expenses related to the May restructuring.

In October 2006, the Company announced its plan to focus its resources on the commercialization of ZYFLO CR, for the chronic treatment of asthma and on the clinical development of the injectable formulation of zileuton and to significantly reduce its net cash expenditures through lower spending on its existing sales force as well as on its discovery and research programs, resulting in a second restructuring. As part of this new business strategy, the Company eliminated 60 positions, or approximately 50% of the Company's workforce at the time. The headcount reduction included 38 sales and marketing employees, 17 research and development employees and 5 employees performing general and administrative functions. The Company substantially completed this restructuring by December 31, 2006.

In connection with the implementation of its October 2006 restructuring, the Company recorded a charge of \$3.0 million in the fourth quarter of 2006, consisting of severance benefits of \$2.3 million, automobile lease termination fees of \$216,000, outplacement service fees of \$26,000 and an impairment charge and other related charges of \$478,000 for laboratory equipment and computer equipment for which the future use was currently uncertain. At December 31, 2006, the Company had \$204,000 remaining in accrued expenses related to the October 2006 restructuring. At December 31, 2007, there are no remaining accrued expenses related to the October restructuring.

In addition, in 2006, the Company had \$972,000 of severance and bonus expenses related to the resignation of its former President and Chief Executive Officer and its former Senior Vice President of Sales and Marketing, which are not included in the restructuring charges above. These amounts were paid in December 2006 in accordance with the contractual terms of the severance and release agreements signed by the individuals.



**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(16) Quarterly Financial Data (Unaudited)**

The following table summarizes selected unaudited condensed quarterly financial information for 2007 and 2006. The Company believes that all adjustments, consisting of normal recurring adjustments considered necessary for a fair presentation, have been included in the selected quarterly information (in thousands, except per share data).

	<b>Quarter Ended December 31,</b>	<b>Quarter Ended September 30,</b>	<b>Quarter Ended June 30,</b>	<b>Quarter Ended March 31,</b>
	<b>(Unaudited) (In thousands except per share data)</b>			
<b>2007</b>				
Revenues:				
Net product sales	\$ 2,697	\$ 3,126	\$ 2,291	\$ 2,894
Revenue under collaboration agreements	31	93	1,136	601
Total revenues	2,728	3,219	3,427	3,495
Cost of goods sold	(1,580)	(1,232)	(680)	(741)
Gross profit	1,148	1,987	2,747	2,754
Total operating expenses	(13,062)	(10,166)	(16,237)	(7,955)
Operating loss	(11,914)	(8,179)	(13,490)	(5,201)
Other income, net	333	393	534	551
Net loss	\$ (11,581)	\$ (7,786)	\$ (12,956)	\$ (4,650)
Net loss per share basic and diluted	\$ (0.27)	\$ (0.18)	\$ (0.30)	\$ (0.11)
<b>2006</b>				
Revenues:				
Net product sales	\$ 1,937	\$ 1,879	\$ 1,809	\$ 1,022
Revenue under collaboration agreements	985	2,499	1,696	1,251
Total revenues	2,922	4,378	3,505	2,273
Cost of goods sold	(561)	(267)	(890)	(504)
Gross profit	2,361	4,111	2,615	1,769
Total operating expenses	(11,694)	(13,549)	(17,679)	(19,228)
Operating loss	(9,333)	(9,438)	(15,064)	(17,459)

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Other income, net		581		558		661		712
Net loss		\$ (8,752)	\$	(8,880)	\$	(14,403)	\$	(16,747)
Net loss per share basic and diluted		\$ (0.22)	\$	(0.26)	\$	(0.42)	\$	(0.49)

Because of the method used in calculating per share data, the quarterly per share data will not necessarily add to the per share data as computed for the year.

F-35

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>March 31, 2008</b>	<b>December 31, 2007</b>
	<b>(Unaudited)</b>	
	<b>(In thousands)</b>	
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 20,239	\$ 33,828
Accounts receivable, net	1,280	1,273
Amount due under collaboration agreements		31
Inventory, net	9,666	5,599
Prepaid expenses and other	1,839	2,174
<b>Total current assets</b>	<b>33,024</b>	<b>42,905</b>
Fixed assets, net	869	1,151
Other assets	287	868
<b>Total assets</b>	<b>\$ 34,180</b>	<b>\$ 44,924</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY:</b>		
Current liabilities:		
Current portion of long-term debt and capital lease obligations	\$	\$ 370
Current portion of accrued license fees	1,860	1,838
Current portion of deferred co-promotion fees	1,880	1,880
Accounts payable	6,566	5,283
Accrued expenses	5,620	7,154
<b>Total current liabilities</b>	<b>15,926</b>	<b>16,525</b>
Long-term portion of accrued license fees, less current portion	1,775	1,754
Long-term portion of deferred co-promotion fees, less current portion	9,353	9,554
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, par value \$0.001; authorized 5,000,000 shares; no shares issued and outstanding		
Common stock, par value \$0.001; authorized 90,000,000 shares; issued and outstanding 42,805,348 shares at March 31, 2008 and December 31, 2007	43	43
Additional paid-in capital	209,247	208,420
Accumulated deficit	(202,151)	(191,372)
Accumulated other comprehensive loss	(13)	
<b>Total stockholders' equity</b>	<b>7,126</b>	<b>17,091</b>

Total liabilities and stockholders' equity	\$ 34,180	\$ 44,924
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The accompanying notes are an integral part of these condensed consolidated financial statements.

F-36

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(Unaudited)</b>	
	<b>(In thousands except share and per share data)</b>	
Revenues:		
Net product sales	\$ 3,333	\$ 2,894
Revenue under collaboration agreements		601
<b>Total revenues</b>	<b>3,333</b>	<b>3,495</b>
Costs and expenses:		
Cost of products sold	1,825	741
Research and development	5,364	2,918
Sales and marketing	3,878	1,982
General and administrative	3,214	3,055
<b>Total costs and expenses</b>	<b>14,281</b>	<b>8,696</b>
Operating loss	(10,948)	(5,201)
Other income (expense):		
Interest income	218	590
Interest expense	(49)	(39)
<b>Total other income</b>	<b>169</b>	<b>551</b>
<b>Net loss</b>	<b>\$ (10,779)</b>	<b>\$ (4,650)</b>
<b>Net loss per share</b>	<b>\$ (0.25)</b>	<b>\$ (0.11)</b>
<b>Basic and diluted weighted-average common shares outstanding</b>	<b>42,805,348</b>	<b>42,456,700</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(Unaudited)</b>	
	<b>(In thousands)</b>	
Cash flows from operating activities:		
Net loss	\$ (10,779)	\$ (4,650)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	115	166
Amortization of premiums on short-term investments and other	43	3
Gain on sale of fixed assets	(108)	(8)
Stock-based compensation expense	827	1,042
Changes in assets and liabilities:		
Accounts receivable	(7)	70
Amount due under collaboration agreements	31	619
Inventory	(4,067)	(574)
Prepaid expenses and other	503	6
Accounts payable	1,283	74
Accrued expenses	(1,534)	(987)
Deferred collaboration revenue and fees		2,430
Deferred product revenue		(1,178)
Deferred co-promotion fees	(201)	
Net cash used in operating activities	(13,894)	(2,987)
Cash flows from investing activities:		
Proceeds from sale of investment	400	
Proceeds from sale of fixed assets	276	26
Purchases of fixed assets	(1)	
Net cash provided by investing activities	675	26
Cash flows from financing activities:		
Proceeds from exercise of stock options		181
Repayments of long-term debt and capital lease obligations	(370)	(278)
Net cash used in financing activities	(370)	(97)
Net decrease in cash and cash equivalents	(13,589)	(3,058)
Cash and cash equivalents at beginning of period	33,828	48,388
Cash and cash equivalents at end of period	\$ 20,239	\$ 45,330

Supplemental disclosures of cash flow information:

Cash paid during the period for:

Interest	\$	9	\$	42
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The accompanying notes are an integral part of these condensed consolidated financial statements.

F-38

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**(1) Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements include the accounts of Critical Therapeutics, Inc. and its subsidiary (the Company), and have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. The Company believes that all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation, have been included. The information included in this quarterly report on Form 10-Q should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and footnotes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2007 as filed with the SEC.

Operating results for the three-month periods ended March 31, 2008 and 2007 are not necessarily indicative of the results for the full year.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in these financial statements include certain judgments regarding revenue recognition, product returns, inventory valuation, accrued and prepaid expenses and valuation of stock-based compensation.

***Management's Plans and Proposed Transaction***

In November 2007, the Company's board of directors announced that it was reviewing a range of strategic alternatives that could result in potential changes to the Company's current business strategy and future operations. As a result of its strategic alternatives process, on May 1, 2008, the Company and Neptune Acquisition Corp., a wholly owned subsidiary of the Company (the Transitory Subsidiary), entered into an Agreement and Plan of Merger (the Merger Agreement) with Cornerstone BioPharma Holdings, Inc. (Cornerstone). This is further discussed in Note 11, Subsequent Events. Under the Merger Agreement, the Transitory Subsidiary will be merged with and into Cornerstone (the Merger), with Cornerstone continuing after the Merger as the surviving corporation and a wholly owned subsidiary of the Company. If the Merger is completed, at the effective time of the Merger, all outstanding shares of Cornerstone's common stock will be converted into and exchanged for shares of the Company's common stock, and all outstanding options, whether vested or unvested, and all outstanding warrants to purchase Cornerstone's common stock will be assumed by the Company and become options and warrants to purchase the Company's common stock. The Merger Agreement provides that in the Merger the Company will issue to Cornerstone stockholders, and assume Cornerstone options and warrants that will represent, an aggregate of approximately 101.5 million shares of the Company's common stock, subject to adjustment as a result of a contemplated reverse stock split of the Company's common stock to occur in connection with the Merger.

***Going Concern Assumption***



The Company has experienced significant operating losses in each year since its inception in 2000, including net losses of \$37.0 million in the year ended December 31, 2007 and \$48.8 million in the year ended December 31, 2006. The Company had net losses of \$10.8 million in the three months ended March 31, 2008 and \$4.7 million in the three months ended March 31, 2007. As of March 31, 2008, the Company had an accumulated deficit of approximately \$202 million. For the year ended December 31, 2007 and the three months ended March 31, 2008, the Company recorded \$11.0 million and \$3.3 million, respectively, of revenue

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

from the sale of ZYFLO<sup>®</sup> (zileuton) tablets ( ZYFLO ) and ZYFLO<sup>®</sup> (zileuton) extended-release tablets ( ZYFLO CR ) and has not recorded revenue from any other product.

Although the size and timing of its future operating losses are subject to significant uncertainty, the Company expects its operating losses to continue over the next several years as it funds its development programs, markets and sells ZYFLO CR and prepares for the potential commercial launch of its product candidates and may never achieve profitability. Since the Company's inception, it has raised proceeds to fund its operations through public offerings of common stock, private placements of equity securities, debt financings, the receipt of interest income, payments from its collaborators, MedImmune and Beckman Coulter, license fees from Innovative Metabolics, Inc. ( IMI ), payments from DEY under its zileuton co-promotion agreement and revenue from sales of ZYFLO CR and ZYFLO.

For the quarter ended March 31, 2008, the Company's net cash used in operating activities was \$13.9 million. Based on our current operating plans, the Company believes that our available cash and cash equivalents and anticipated cash received from product sales will be sufficient to fund anticipated levels of operations for the foreseeable future. If the Company's existing resources are insufficient to satisfy its liquidity requirements, either under its current operating plan or any new operating plan it may adopt, it may need to raise additional external funds through collaborative arrangements and public or private financings. Additional financing may not be available to the Company on acceptable terms or at all.

These matters raise substantial doubt about the Company's ability to continue as a going concern and, therefore, the Company may be unable to realize its assets and discharge its liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts nor to amounts and classification of liabilities that may be necessary should the Company be unable to continue as a going concern.

***Recent Accounting Pronouncements***

In November 2007, the Financial Accounting Standards Board's ( FASB ) Emerging Issues Task Force ( EITF ) issued EITF Issue No. 07-01, *Accounting for Collaborative Arrangements* ( EITF 07-01 ). EITF 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable generally accepted accounting principles ( GAAP ) or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. Further, EITF 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer or analogous relationship subject to EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer*. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of EITF 07-01 to have a material impact on its financial statements and results of operations.

In June 2007, the EITF issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3

is effective for fiscal years beginning after December 15, 2007. The initial adjustment to reflect the effect of applying this EITF as a change in accounting principle would be accounted for as a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. The adoption of EITF 07-03 did not have a material impact on the Company's financial statements and results of operations.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

In December 2007, the FASB issued Statement of Financial Accounting Standards ( SFAS ) No. 141(R), *Business Combinations* ( SFAS 141(R) ). SFAS 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values and changes other practices under SFAS No. 141, *Business Combinations*, some of which could have a material impact on how an entity accounts for its business combinations. SFAS 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008 and is applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009. The provisions of SFAS 141(R) will only impact the Company if it is party to a business combination after the pronouncement has been adopted.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interest in Consolidated Financial Statements – an amendment of ARB No. 51* ( SFAS 160 ). SFAS 160 requires entities to report non-controlling minority interests in subsidiaries as equity in consolidated financial statements. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. SFAS 160 is applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for presentation and disclosure requirements, which are applied retrospectively for all periods presented. The Company does not expect the adoption of SFAS 160 to have a material impact on its financial statements and results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of SFAS 115* ( SFAS 159 ). SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which a company has chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company was required to adopt SFAS 159 on January 1, 2008. The adoption of SFAS 159 did not have a material impact on the Company's financial statements and results of operations, as the Company has not elected to measure any financial assets or liabilities at fair value.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ( SFAS 157 ). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. In February 2008, the FASB issued Staff Position No. FAS 157-2 ( FSP 157-2 ) that defers the effective date of applying the provisions of SFAS 157 to the fair value measurement of nonfinancial assets and nonfinancial liabilities until fiscal years beginning after November 15, 2008. The Company was required to adopt the provisions of SFAS 157 that pertain to financial assets and liabilities on January 1, 2008 and has included the now expanded disclosures in Note 3. The Company is currently evaluating the effect FSP 157-2 will have on its financial statements and results of operations.

**(2) Revenue Recognition**

***Revenue Recognition***

The Company recognizes revenue in accordance with the SEC Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* ( SAB 101 ) as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition* ( SAB 104 ). Specifically, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. The Company's revenue is currently derived from product sales of its

F-41

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

commercially marketed products, ZYFLO CR and ZYFLO, and its collaboration and license agreements. The collaboration and license agreements provide for various payments, including research and development funding, license fees, milestone payments and royalties. In addition, the Company's product sales are subject to various rebates, discounts and incentives that are customary in the pharmaceutical industry.

*Net product sales*

The Company sells ZYFLO CR and ZYFLO primarily to pharmaceutical wholesalers, distributors and pharmacies. The Company commercially launched ZYFLO in October 2005 and ZYFLO CR in September 2007. The Company authorizes returns for damaged products and exchanges for expired products in accordance with its return goods policy and procedures, and has established allowances for such amounts at the time of sale. The Company is obligated to accept from customers the return of products that are within six months of their expiration date or up to 12 months beyond their expiration date. The Company recognizes revenue from product sales in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, which requires the amount of future returns to be reasonably estimated at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns, estimated rebates in connection with contracts relating to managed care, Medicaid, Medicare, and estimated chargebacks from distributors and prompt payment and other discounts.

The Company establishes allowances for estimated product returns, rebates and chargebacks primarily based on several factors, including the actual historical product returns, the Company's estimate of inventory levels of the Company's products in the distribution channel, the shelf-life of the product shipped, competitive issues such as new product entrants and other known changes in sales trends. The Company evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve accordingly.

The Company's estimates of product returns, rebates and chargebacks require management's subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. If actual future payments for returns, rebates, chargebacks and other discounts exceed the estimates the Company made at the time of sale, its financial position, results of operations and cash flows would be negatively impacted.

As of March 31, 2008 and 2007, the Company's allowances for ZYFLO CR and ZYFLO product returns were \$286,000 and \$138,000, respectively. Prior to the first quarter of 2007, the Company deferred the recognition of revenue on ZYFLO product shipments to wholesale distributors and pharmacies until units were dispensed through patient prescriptions, as the Company was unable to reasonably estimate the amount of future product returns. Units dispensed are not generally subject to return. In the first quarter of 2007, the Company began recording revenue upon shipment to third parties, including wholesalers, distributors and pharmacies, and providing a reserve for potential returns from these third parties as sufficient history existed to make such estimates. In connection with this change in estimate, the Company recorded an increase in net product sales in the three months ended March 31, 2007 related to the recognition of revenue from product sales that had been previously deferred, net of an estimate for remaining product returns. This change in estimate totaled approximately \$953,000. The Company recorded \$2.6 million in net product sales of ZYFLO CR in the first quarter of 2008. The Company anticipates that the rate of return for ZYFLO CR will be comparable to the historical rate of return used for ZYFLO. As a result, the Company recognizes revenue for sales of ZYFLO CR upon shipment to third parties and records a reserve for potential returns. In the first quarter of 2008, primarily as a result of stronger than expected ZYFLO prescriptions, the Company reduced its product return

reserve for ZYFLO by \$440,000.

*Revenue under collaboration and license agreements*

Under the Company's collaboration agreements with MedImmune and Beckman Coulter, the Company is entitled to receive non-refundable license fees, milestone payments and other research and development

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

payments. Payments received are initially deferred from revenue and subsequently recognized in the Company's statements of operations when earned. The Company must make significant estimates in determining the performance period and periodically review these estimates, based on joint management committees and other information shared by the Company's collaborators. The Company recognizes these revenues over the estimated performance period as set forth in the contracts based on proportional performance adjusted from time to time for any delays or acceleration in the development of the product. For example, a delay or acceleration of the performance period by the Company's collaborator may result in further deferral of revenue or the acceleration of revenue previously deferred. Because MedImmune and Beckman Coulter can each cancel its agreement with the Company, the Company does not recognize revenues in excess of cumulative cash collections.

Under the Company's license agreement with IMI, the Company licensed to IMI patent rights and know-how relating to the mechanical and electrical stimulation of the vagus nerve. Under the agreement with IMI, the Company received an initial license fee of \$500,000 in cash and IMI junior preferred stock valued at \$500,000 in connection with IMI's first financing. However, under its license agreement with The Feinstein Institute for Medical Research (formerly known as The North Shore-Long Island Jewish Research Institute (The Feinstein Institute)), the Company was obligated to pay The Feinstein Institute \$100,000 of this cash payment and IMI junior preferred stock valued at \$100,000. The Company included in revenue under collaboration and license agreements in 2007 the \$1.0 million total license fee that the Company received from IMI and included the payments of \$100,000 in cash and IMI junior preferred stock valued at \$100,000 that the Company made to The Feinstein Institute in research and development expenses. These amounts were recorded in the second quarter of 2007. Under the license agreement, IMI also has agreed to pay the Company \$1.0 million, excluding a \$200,000 payment that the Company would be obligated to pay The Feinstein Institute, upon full regulatory approval of a licensed product by the FDA or a foreign counterpart agency and royalties based on a net sales of licensed products and methods by IMI and its affiliates.

On March 14, 2008, the Company sold the 400,000 shares of junior preferred stock issued to it by IMI in May 2007 in connection with IMI's first financing for an aggregate purchase price of \$400,000. The Company sold these shares of junior preferred stock to two investors which had previously participated in IMI's first financing. The purchase price is subject to adjustments if these investors sell or receive consideration for these shares of junior preferred stock pursuant to an acquisition of IMI prior to February 1, 2009 at a price per share greater than the price they paid the Company.

At March 31, 2008, the Company's accounts receivable balance of \$1.3 million was net of allowances of \$30,000. At December 31, 2007, the Company's accounts receivable balance of \$1.3 million was net of allowances of \$29,000.

**(3) Cash Equivalents and Investments**

The Company considers all highly-liquid investments with original maturities of three months or less when purchased to be cash equivalents.

At March 31, 2008, the Company held \$287,000 in auction rate security with a AAA credit rating upon purchase. The Company has been informed that there is insufficient demand at auction for these security. As a result, this amount is currently not liquid and may not become liquid unless the issuer is able to refinance it. The Company has classified its \$287,000 in auction rate security as a long-term investment and has included the amount in other assets on the



Company's accompanying balance sheet. The unrealized gain (loss) during the period is recorded as an adjustment to stockholders' equity. The cost of the debt securities, if any, is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization or accretion is included in interest income (expense) in the corresponding period.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)  
(Unaudited)**

As a result of the adoption of SFAS 157 as of January 1, 2008, the Company is now required to provide additional disclosures as part of its financial statements.

SFAS 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of March 31, 2008 (in thousands):

	Total Carrying Value at March 31, 2008	Fair Value Measurements at March 31, 2008 Using Significant		
		Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available for sale securities:				
U.S. government-backed securities	\$ 3,561	\$ 3,561	\$	\$
Commercial paper	1,199		1,199	
Auction rate security	287			287
Total assets measured at fair value	\$ 5,047	\$ 3,561	\$ 1,199	\$ 287

U.S. government-backed securities and commercial paper are valued using a market approach based upon the quoted market prices of identical instruments when available or other observable inputs such as trading prices of identical instruments in inactive markets. Scheduled maturity dates of U.S. government-backed securities and commercial paper as of March 31, 2008, had original maturities of less than 90 days and therefore investments were classified as cash and cash equivalents.

The Company's auction rate security instrument is classified as an available for sale security and reflected at fair value. However, due to recent events in credit markets, the auction for this security failed during first quarter of 2008. Therefore, the fair value of this security is estimated utilizing a discounted cash flow analysis or other type of valuation model as of March 31, 2008. This analysis considers, among other items, the collateralization underlying the

security investments, the creditworthiness of the counterparty, the timing of expected future cash flows and the expectation of the next time the security is expected to have a successful auction.

As a result of the temporary decline in fair value for the Company's auction rate security, which the Company attributes to liquidity issues rather than credit issues, it has recorded an unrealized loss of \$13,000 to accumulated other comprehensive income.

**(4) Research and License Agreements**

In December 2003, the Company entered into an agreement to in-license the controlled-release formulation and the injectable formulation of zileuton from Abbott Laboratories and entered into an agreement with a subsidiary of SkyePharma PLC ( SkyePharma ), to in-license the controlled-release technology relating to zileuton from SkyePharma. Under these agreements, the Company is required to make milestone payments for

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

successful completion of the technology transfer, filing and approval of the product in the United States and commercialization of the product. In May 2007, the Company received approval by the FDA of the new drug application ( NDA ) for ZYFLO CR. As a result of the FDA approval, the Company paid \$3.1 million under these agreements in June 2007, and accrued an additional \$1.8 million and \$1.7 million that will be due on the first and second anniversary, respectively, of the FDA's approval of ZYFLO CR. The amounts due on the first and second anniversary of the FDA's approval were accrued at the present value of the total \$3.8 million owed, and the accretion of the discount is included in interest expense. The \$3.1 million paid as a result of the FDA approval of ZYFLO CR and the accrued \$1.8 million and \$1.7 million that will be due on the first and second anniversary, respectively, of the FDA's approval of ZYFLO CR were included in the Company's research and development expenses in the second quarter of 2007. For the three months ended March 31, 2008, the Company recorded interest expense of \$43,000 related to the accretion of the discount.

**(5) Inventory**

Inventory is stated at the lower of cost or market, with cost determined under the first-in, first-out ( FIFO ) method. As of March 31, 2008, the Company held \$9.7 million in inventory to be used for commercial sales related to its commercial product, ZYFLO CR. The Company analyzes its inventory levels quarterly and records reserves for inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. Expired inventory is disposed of and the related costs are written off. At March 31, 2008, the Company had an inventory reserve of \$1.2 million. The inventory reserve relates to certain batches that did not meet the Company's product release specifications for ZYFLO CR. Inventory consisted of the following at March 31, 2008 and December 31, 2007, respectively (in thousands):

	<b>March 31, 2008</b>	<b>December 31, 2007</b>
Raw material	\$ 6,301	\$ 2,587
Work in process	4,197	3,062
Finished goods	361	766
Total inventory	10,859	6,415
Less: reserve	(1,193)	(816)
Inventory, net	\$ 9,666	\$ 5,599

***Risk and uncertainties***

The Company currently purchases zileuton active pharmaceutical ingredient ( API ) for its commercial requirements for ZYFLO CR from a single source. In addition, the Company currently contracts with single parties for the manufacture of uncoated ZYFLO CR tablets and for the coating and packaging of ZYFLO CR tablets. The disruption or termination of the supply of the API, a significant increase in the cost of the API from this single source or the

disruption or termination of the manufacturing of the commercial product would have a material adverse effect on the Company's business, financial position and results of operations.

**(6) Comprehensive Loss**

Comprehensive loss is the total of net loss and all other non-owner changes in equity. The difference between net loss, as reported in the accompanying condensed consolidated statements of operations for the three months ended March 31, 2008 and 2007, and comprehensive loss is the unrealized gain (loss) on investments for the period. Total comprehensive loss was \$10.8 million and \$4.6 million for the three months ended

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

March 31, 2008 and 2007, respectively. The unrealized gain (loss) on investments is the only component of accumulated other comprehensive loss in the accompanying condensed consolidated balance sheet.

**(7) Stock-Based Compensation**

All stock-based awards are accounted for at their fair market value in accordance with SFAS No. 123 (revised 2004), *Share-Based Payment* ( SFAS 123(R) ) and EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.

Stock option activity for the three-month period ended March 31, 2008 was as follows:

	<b>Number of Shares</b>	<b>2008 Weighted-Average Exercise Price per Share</b>
Outstanding January 1	5,020,903	\$ 4.20
Granted	12,000	0.90
Exercised		
Cancelled	(888,119)	3.66
Outstanding March 31	4,144,784	\$ 4.31
Vested and Expected to Vest March 31	3,759,083	\$ 4.34
Exercisable March 31	2,514,974	\$ 4.75

The weighted-average remaining contractual term and the aggregate intrinsic value for options outstanding at March 31, 2008 were 6.2 years and \$6,000, respectively. The weighted-average remaining contractual term and the aggregate intrinsic value for options exercisable at March 31, 2008 were 4.9 years and \$6,000, respectively. The weighted-average exercise price and the number of options vested or expected to vest at March 31, 2008 were 5.9 years and \$6,000, respectively. There were no options exercised during the three months ended March 31, 2008.

The total fair value of the shares vested and unexercised and expensed during the three months ended March 31, 2008 was \$168,000. As of March 31, 2008, there was \$4.9 million of total unrecognized compensation expense related to unvested share-based compensation awards granted under the Company's stock plans, which is expected to be recognized over a weighted-average period of 2.0 years.

The Company anticipates recording additional stock-based compensation expense of \$2.0 million in the remaining three quarters of 2008, \$2.0 million in 2009 and \$828,000 thereafter relating to the amortization of unrecognized compensation expense as of March 31, 2008. These anticipated compensation expenses do not include any adjustment

for new or additional options to purchase common stock granted to employees.

Option valuation models require the input of highly subjective assumptions. The Company has computed the impact under SFAS 123(R) for options granted using the Black-Scholes option-pricing model for the three months ended March 31, 2008 and 2007. The Company increased its expected volatility assumption for the three months ended March 31, 2008 to 73% from 66% in the corresponding period of 2007. The rate is based on the Company's actual historical volatility since its initial public offering. The expected life of options

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

granted was estimated using the simplified method calculation as prescribed by SEC Staff Accounting Bulletin No. 110. The assumptions used and weighted-average information are as follows:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
Risk free interest rate	2.8%	4.6 %
Expected dividend yield	0%	0 %
Expected forfeiture rate	10.6%	10.2 %
Expected life	6.25years	6.25 years
Expected volatility	73%	66 %
Weighted-average fair value of options granted equal to fair value	\$ 0.60	\$ 1.35

**(8) Basic and Diluted Loss per Share**

Basic and diluted net loss per common share is calculated by dividing the net loss by the weighted-average number of unrestricted common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share, because the effects of potentially dilutive securities are anti-dilutive for all periods presented. Anti-dilutive securities that are not included in the diluted net loss per share calculation aggregated 12,027,341 and 12,908,520 as of March 31, 2008 and 2007, respectively. These anti-dilutive securities consist of outstanding stock options, warrants, and unvested restricted common stock as of March 31, 2008 and 2007.

**(9) Commitments and Contingencies**

The Company has entered into various agreements with third parties and certain related parties in connection with research and development activities relating to its existing product candidates as well as discovery efforts relating to potential new product candidates. These agreements include costs for research and development and license agreements that represent the Company's fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that the Company may be required to pay under its license agreements upon the achievement of scientific, regulatory and commercial milestones that may become payable depending on the progress of scientific development and regulatory approvals, including milestones such as the submission of an IND to the FDA, similar submissions to foreign regulatory authorities and the first commercial sale of the Company's products in various countries. These agreements include costs related to manufacturing, clinical trials and preclinical studies performed by third parties. The estimated amount that may be incurred in the future under these agreements totals approximately \$29.9 million as of March 31, 2008. The amount and timing of these commitments may change, as they are largely dependent on the rate of enrollment in the Company's clinical trials and timing of the development of the Company's product candidates. As of March 31, 2008, the Company had \$25,000 and \$1.7 million included in prepaid expenses and accrued expenses, respectively, related to its research and development agreements on the accompanying condensed consolidated balance sheet. These research and development expenses are accounted for as such costs are incurred. In addition, as of March 31, 2008, the Company had \$3.6 million in accrued license fees representing the net present value of the Company's milestone



obligations due on the first and second anniversary of the FDA's approval of ZYFLO CR. In addition, at March 31, 2008, the Company accrued approximately \$1.1 million in contractual costs as a result of the Company's termination of a Phase IV clinical trial for ZYFLO CR. These accrued license fees and termination costs are included in the accompanying condensed consolidated balance sheet.

In addition, on August 20, 2007, the Company entered into an agreement with Jagotec, a subsidiary of SkyePharma PLC, under which Jagotec agreed to manufacture and supply bulk uncoated tablets of ZYFLO CR to the Company for commercial sale. The Company previously had contracted with Jagotec for the manufacture of ZYFLO CR for clinical trials and regulatory review. Under the terms of the prior agreement,

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

the Company and Jagotec had agreed to negotiate a commercial manufacturing agreement for ZYFLO CR. SkyePharma has guaranteed the performance by Jagotec of all obligations under the commercial manufacturing agreement. The Company has agreed to purchase minimum quantities of ZYFLO CR during each 12-month period for the first five years following marketing approval of ZYFLO CR by the FDA. For the term of the contract, the Company has agreed to purchase specified amounts of its requirements for ZYFLO CR from Jagotec. The commercial manufacturing agreement has an initial term of five years beginning on May 22, 2007, and will automatically continue thereafter, unless the Company provides Jagotec with 24-months prior written notice of termination or Jagotec provides the Company with 36-months prior written notice of termination. The Company also entered into a manufacturing and supply agreement with Rhodia Pharma Solutions, which was assigned to Shasun, for commercial production of the API for ZYFLO and ZYFLO CR, subject to specified limitations, through December 31, 2009. Under this agreement, the Company committed to purchase minimum amounts of API in the first quarter of 2008. In addition, the Company has agreed to purchase specified quantities of API in 2008 and 2009 with a portion subject to the right of cancellation with a termination fee. The API purchased from Shasun currently has a shelf-life of 36 months. The Company evaluates the need to provide reserves for contractually committed future purchases of inventory that may be in excess of forecasted future demand. In making these assessments, the Company is required to make judgments as to the future demand for current or committed inventory levels and as to the expiration dates of its product. As of March 31, 2008, no reserves have been recorded for purchase commitments.

In May 2007, the Company entered into a three year manufacturing services agreement with Patheon Pharmaceuticals Inc. ( Patheon ), under which Patheon agreed to coat, conduct quality control and quality assurance and stability testing and package commercial supplies of ZYFLO CR in tablet form. Under this agreement, the Company is responsible for supplying uncoated ZYFLO CR tablet cores to Patheon. The Company has agreed to purchase at least 50% of its requirements for such manufacturing services for ZYFLO CR for sale in the United States from Patheon each year for the term of the agreement.

In addition, in accordance with its co-promotion agreement with DEY, the Company has entered into advertising and promotional contracts related to its marketing support for ZYFLO CR. The estimated amount that may be incurred in the future under these agreements totals approximately \$7.3 million as of March 31, 2008.

The Company is also party to a number of agreements that require it to make milestone payments, royalty payments on net sales of the Company's products and payments on sublicense income received by the Company. In addition, from time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company is not a party to any pending material litigation or other material legal proceedings and was not a party to any such litigation or proceedings during any of the periods presented.

**(10) DEY Co-Promotion and Marketing Services Agreements**

On March 13, 2007, the Company entered into an agreement with DEY under which the Company and DEY agreed to jointly promote ZYFLO and ZYFLO CR. Under the co-promotion and marketing services agreement, the Company granted DEY an exclusive right and license to promote and detail ZYFLO and ZYFLO CR in the United States, together with the Company. Under the co-promotion agreement, DEY paid the Company a non-refundable upfront payment of \$3.0 million in March 2007, a milestone payment of \$4.0 million in June 2007 following approval by the

FDA of the NDA for ZYFLO CR in May 2007 and a milestone payment of \$5.0 million in December 2007 following the commercial launch of ZYFLO CR. Under the co-promotion agreement, the Company will pay DEY a commission on quarterly net sales of ZYFLO and ZYFLO CR, after third-party royalties, in excess of \$1.95 million. From the date DEY began detailing ZYFLO through the commercial launch of ZYFLO CR, the commission rate was 70%, following the commercial launch of ZYFLO CR in September 2007 through December 31, 2010, the commission rate is

F-48

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**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

35% and from January 1, 2011 through December 31, 2013, the commission rate is 20%. The co-promotion agreement expires on December 31, 2013 and may be extended upon mutual agreement by the parties.

The Company has deferred the \$12 million in aggregate payments received to date and is amortizing these payments over the term of the agreement. The amortization of the upfront and milestone payments will be offset by the co-promotion fees paid to DEY for promoting ZYFLO and ZYFLO CR. The Company records all ZYFLO and ZYFLO CR sales generated by the combined sales force and records any co-promotion fees paid to DEY and the amortization of the upfront and milestone payments as sales and marketing expenses. For the three months ended March 31, 2008, approximately \$200,000 was amortized from the deferred co-promotion fees representing the amount earned by DEY during this period.

On June 25, 2007, the Company entered into a definitive agreement with DEY to jointly promote DEY's product PERFOROMIST<sup>™</sup> (formoterol fumarate) Inhalation Solution ( PERFOROMIST ), for the treatment of chronic obstructive pulmonary disease, or COPD. In October 2007, the Company announced that it commercially launched PERFOROMIST with DEY. Under the agreement, DEY agreed to pay the Company a commission on retail sales of PERFOROMIST above a specified baseline. The agreement has a term expiring on December 31, 2013, which may be extended upon mutual agreement by the parties.

**(11) Subsequent Events**

***Proposed Merger with Cornerstone BioPharma Holdings, Inc.***

As described in Note 1, Basis of Presentation, on May 1, 2008, the Company, the Transitory Subsidiary and Cornerstone entered into the Merger Agreement. If the Merger is completed, at the effective time of the Merger, all outstanding shares of Cornerstone's common stock will be converted into and exchanged for shares of our common stock, and all outstanding options, whether vested or unvested, and all outstanding warrants to purchase Cornerstone's common stock will be assumed by the Company and become options and warrants to purchase the Company's common stock. The Merger Agreement provides that in the Merger the Company will issue to Cornerstone stockholders, and assume Cornerstone options and warrants that will represent, an aggregate of approximately 101.5 million shares of the Company's common stock, subject to adjustment as a result of a contemplated reverse stock split of the Company's common stock to occur in connection with the Merger. Immediately following the effective time of the Merger, Cornerstone's stockholders will own approximately 70 percent, and the Company's current stockholders will own approximately 30 percent, of the Company's common stock, after giving effect to shares issuable pursuant to Cornerstone's outstanding options and warrants, but without giving effect to any shares issuable pursuant to the Company's outstanding options and warrants. The exchange ratio per share of Cornerstone's common stock will be based on the number of shares of Cornerstone's common stock outstanding immediately prior to the effective time of the merger and will not be calculated until that time.

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

Immediately prior to the effective time of the Merger, the Company has agreed to effect a reverse stock split of its common stock whereby each issued and outstanding share of its common stock will be reclassified and combined into a fractional number of shares of common stock. The reverse stock split ratio is to be mutually agreed upon by the Company and Cornerstone. The reverse stock split is necessary so that as of the effective time of the Merger the Company will satisfy the minimum bid price requirement pursuant to NASDAQ's initial listing standards.

**CRITICAL THERAPEUTICS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

The Merger Agreement provides for the payment of a termination fee of \$1.0 million by each of the Company 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, the Company has agreed to reimburse Cornerstone for up to \$150,000 in expenses and Cornerstone has agreed to reimburse the Company for up to \$100,000 in expenses.

***May and June 2008 Restructuring Plans***

As part of its efforts to reduce its operating expenditures, on May 8, 2008, the Company announced that it had eliminated six positions, or approximately 8% of the Company's workforce. The headcount reduction primarily affects the Company's research and development group. In addition, on June 12, 2008, the Company announced that it had eliminated an additional 15 positions, or approximately 23% of its remaining workforce during the month of June. The June 2008 headcount reductions primarily affect employees performing sales and development functions. The Company expects to consider further reductions in its headcount in additional areas of its business in the future to conserve cash and reduce expenses. The nature, extent and timing of future reductions will be made based on the Company's business needs and financial resources.

In connection with the implementation of its May 8, 2008 and June 12, 2008 restructuring plans, the Company expects to record a charge of approximately \$1.2 million of severance benefits in the second quarter of 2008.

***Inventory Valuation***

As disclosed in Note 5, the Company had recorded as of March 31, 2008 an inventory reserve of \$1.2 million related to certain batches of ZYFLO CR that did not meet the Company's product release specifications for ZYFLO CR. In addition, in conjunction with its three third-party manufacturers for zileuton API, tablet cores and coating and release, the Company initiated an investigation to determine the cause. To date, the investigation has not identified a clear source of cause and the investigation is on-going. In June 2008, the Company identified seven additional batches of tablet cores of ZYFLO CR that were on quality assurance hold and that could not complete manufacturing within the NDA-specified manufacturing timelines and one additional batch that did not meet the Company's product release specifications for ZYFLO CR. As a result, the Company recorded an additional inventory reserve of approximately \$1.3 million as of June 30, 2008.

**INDEX TO CORNERSTONE S CONSOLIDATED FINANCIAL STATEMENTS**

**TABLE OF CONTENTS**

	<b>Page</b>
<b>CORNERSTONE CONSOLIDATED FINANCIAL STATEMENTS</b>	
Report of Independent Registered Public Accounting Firm	F-52
Consolidated Balance Sheets at December 31, 2007 and December 31, 2006	F-53
Consolidated Statements of Operations for the Years ended at December 31, 2007, December 31, 2006 and December 31, 2005	F-54
Consolidated Statements of Stockholders' Deficit and Comprehensive Income (Loss) for the Years ended at December 31, 2007, December 31, 2006 and December 31, 2005	F-55
Consolidated Statements of Cash Flows for the Years ended at December 31, 2007, December 31, 2006 and December 31, 2005	F-56
Notes to Consolidated Financial Statements	F-58
Cornerstone Consolidated Financial Statements (Unaudited)	
Consolidated Balance Sheets at March 31, 2008 (Unaudited) and December 31, 2007	F-85
Consolidated Statements of Operations for the Three Months ended at March 31, 2008 and March 31, 2007 (Unaudited)	F-86
Consolidated Statements of Cash Flows for the Three Months ended at March 31, 2008 and at March 31, 2007 (Unaudited)	F-87
Notes to Consolidated Financial Statements	F-88

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders  
Cornerstone BioPharma Holdings, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Cornerstone BioPharma Holdings, Inc. and Subsidiaries (a Delaware corporation) as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' deficit and comprehensive income (loss), and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cornerstone BioPharma Holdings, Inc. as of December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America.

/s/ GRANT THORNTON LLP

Raleigh, North Carolina  
July 11, 2008



**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands, except share and per share data)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 241	\$ 116
Marketable security (restricted in 2006)	8	153
Accounts receivable, net	6,529	2,280
Amounts due from related parties	648	152
Inventories, net	2,998	1,847
Prepaid expenses	278	266
 Total current assets	 10,702	 4,814
 Property and equipment, net	 209	 217
Other assets:		
Product rights, net	4,936	5,456
Amounts due from related parties	29	28
Deposits	33	67
 Total other assets	 4,998	 5,551
 Total assets	 \$ 15,909	 \$ 10,582
<b>Liabilities</b>		
Current liabilities:		
Accounts payable	\$ 2,214	\$ 1,432
Accrued expenses	11,163	10,142
Current portion of license agreement liability	576	720
Line of credit	1,750	1,750
Income taxes payable	130	
 Total current liabilities	 15,833	 14,044
Long-term liabilities:		
License agreement liability, less current portion	2,959	970
Note payable, related party	9,412	9,412
 Total long-term liabilities	 12,371	 10,382

Total liabilities	28,204	24,426
<b>Stockholders deficit</b>		
Common stock \$0.0001 par value, 50,000,000 shares authorized, 24,926,150 shares issued and outstanding	2	2
Additional paid-in capital	801	
Accumulated other comprehensive loss		(178)
Accumulated deficit	(13,098)	(13,668)
Total stockholders deficit	(12,295)	(13,844)
Total liabilities and stockholders deficit	\$ 15,909	\$ 10,582

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands)</b>		
Net revenues	\$ 28,071	\$ 22,117	\$ 17,470
Costs and expenses:			
Cost of product sales	3,300	2,151	3,437
Sales and marketing	10,391	7,120	13,889
Royalties	3,409	1,663	1,933
General and administrative	4,106	3,679	4,881
Research and development	948	249	266
Amortization and depreciation	3,231	2,704	1,939
Other charges	245	3,581	1,000
Total costs and expenses	25,630	21,147	27,345
Income (loss) from operations	2,441	970	(9,875)
Other expenses:			
Interest expense, net	(1,410)	(1,240)	(1,557)
Loss on marketable security	(324)		
Other expenses	(7)	(35)	(6)
Total other expenses	(1,741)	(1,275)	(1,563)
Income (loss) before income taxes	700	(305)	(11,438)
Provision for income taxes	130		
Net income (loss)	\$ 570	\$ (305)	\$ (11,438)

## CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS  
DEFICIT AND COMPREHENSIVE INCOME (LOSS)  
YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005**

	Common Shares	Stock Amount	Subscription Receivable	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders Deficit	Total Comprehensive Income (Loss)
	(In thousands, except share data)							
Balance as of December 31, 2004	25,000,000	\$ 2	\$ (1)	\$ 47		\$ (1,702)	\$ (1,654)	
Issuance of shares of common stock to directors	200,000			20			20	
Stock-based compensation				4			4	
Issuance of warrants to purchase common stock				164			164	
Collection of stock subscription receivable			1				1	
Net loss						(11,438)	(11,438)	\$ (11,438)
Total comprehensive loss								\$ (11,438)
Balance as of December 31, 2005	25,200,000	2		235		(13,140)	(12,903)	
Exercise of options to purchase common stock	101,150			10			10	
Redemption of restricted common stock	(375,000)							
Stock-based compensation				78			78	
Issuance of warrants to purchase common stock				1			1	
					\$ (178)		(178)	\$ (178)

Unrealized loss on investment							
Repurchase of warrants			(324)		(223)		(547)
Net loss					(305)		(305)
							(305)
Total comprehensive loss							\$ (483)
Balance as of December 31, 2006	24,926,150	2		(178)	(13,668)		(13,844)
Stock-based compensation			293				293
Issuance of warrants to purchase common stock			508				508
Unrealized loss on investment				(145)			(145)
							\$ (145)
Reclassification adjustment for losses on investments included in net income				323			323
							323
Net income					570		570
							570
Total comprehensive income							\$ 748
Balance as of December 31, 2007	24,926,150	\$ 2	\$	\$ 801	\$	\$ (13,098)	\$ (12,295)

## CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands)</b>		
<b>Cash flows from operating activities</b>			
Net income (loss)	570	(305)	(11,438)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Amortization and depreciation	3,231	2,704	1,939
Amortization of debt discount			241
Issuance of common stock warrants and options for services	801	79	
Loss on marketable security	323		
Forfeiture of product rights		1,663	
Stock received for royalties		(332)	
Changes in operating assets and liabilities:			
Accounts receivable, net	(4,249)	(299)	1,844
Amounts due from related parties	117	(186)	(100)
Inventories, net	(1,151)	(1,629)	690
Prepaid expenses	(12)	(153)	229
Accounts payable	783	(1,117)	(432)
Accrued expenses	1,020	525	7,611
Income taxes payable	130		
Net cash provided by operating activities	1,563	950	610
<b>Cash flows from investing activities</b>			
Advances to related parties	(876)	(1,193)	(2,567)
Proceeds from collection of advances to related parties	262	1,053	1,480
Purchase of property and equipment	(64)	(57)	(125)
Purchase of product rights	(75)	(500)	(1,500)
Collection of deposits	50		
Release of restricted cash			68
Payment of deposits	(15)	(55)	(4)
Proceeds from sale of property and equipment		38	
Net cash used in investing activities	(718)	(714)	(2,648)
<b>Cash flows from financing activities</b>			
Principal payments on license agreement liability	\$ (720)	\$ (250)	\$
Proceeds from line of credit	9,000	8,100	3,500
Principal payments on line of credit	(9,000)	(6,850)	(3,000)
Principal payments on notes payable		(1,542)	(1,512)
Repurchase of warrants		(547)	
Exercise of common stock options		10	

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Proceeds from collection of stock subscription receivable			1
Net cash used in financing activities	(720)	(1,079)	(1,011)
Net increase (decrease) in cash and cash equivalents	125	(843)	(3,049)

F-56

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	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands)</b>		
<b>Cash and cash equivalents as of beginning of year</b>	116	959	4,008
<b>Cash and cash equivalents as of end of year</b>	\$ 241	\$ 116	\$ 959
<b>Supplemental disclosure of cash flow information</b>			
Cash paid during the year for interest	\$ 433	\$ 187	\$ 703
<b>Supplemental schedule of non-cash investing and financing activities</b>			
Product rights acquired through issuance of a license agreement	\$ 2,565	\$ 1,940	\$
Note payable plus accrued interest exchanged for inventory, note receivable and advances due from related party	\$	\$ 5,429	\$
Issuance of a common stock warrant for product license rights	\$	\$	\$ 164



**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Nature of Operations**

Cornerstone BioPharma Holdings, Inc., together with its subsidiaries (collectively, the Company), is a specialty pharmaceutical company focused on acquiring, developing and commercializing prescription products for the respiratory market. The Company'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.

**Business Risk and Liquidity**

The Company's consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. From inception in 2004 through 2006, the Company incurred operating losses, including net losses of \$305,000 in 2006 and \$11.4 million in 2005. The Company's net income was \$570,000 in the year ended December 31, 2007. As of December 31, 2007, the Company's accumulated deficit was \$13.1 million.

The Company expects to continue to incur significant development and commercialization expenses as it advances the development of its product candidates; seeks regulatory approvals for its product candidates that successfully complete clinical testing; and expands its sales team and marketing capabilities to prepare for the commercial launch of future products, subject to approval by the U.S. Food and Drug Administration (FDA). The Company also expects to incur additional expenses to add operational, financial and management information systems and personnel, including personnel to support its product development efforts. Accordingly, the Company will need to increase its revenues to be able to sustain and increase its profitability on an annual and quarterly basis. There is no assurance that the Company will be able to do so. The Company's failure to achieve consistent profitability could impair its ability to raise capital, expand its business, diversify its product offerings and continue its operations.

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

As of December 31, 2007, the Company had approximately \$241,000 of cash and cash equivalents on hand and borrowing availability of approximately \$2.25 million under its line of credit. Based on its current operating plans, the Company believes that its existing cash and cash equivalents, revenues from product sales and borrowing availability under the 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. However, lower than projected cash flows as a result of reduced net product sales or increased expenses could require the Company to raise additional capital in order to sustain its operations. There can be no assurance that management's plan will be executed as anticipated.

**Principles of Consolidation**

The Company's consolidated financial statements include the accounts of Cornerstone BioPharma Holdings, Inc., a Delaware corporation, Cornerstone BioPharma, Inc., a Nevada corporation, Cornerstone Biopharma, Ltd., an Anguilla international business company and Aristos Pharmaceuticals, Inc., a Delaware corporation.

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Cornerstone Biopharma, Ltd. was dissolved in September 2007. All significant intercompany accounts and transactions have been eliminated.

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ( GAAP ) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in the Company's consolidated financial statements include certain judgments regarding revenue recognition, product rights, inventory valuation, accrued expenses and stock-based compensation.

**Segment and Geographic Information**

The Company follows the provisions of Statement of Financial Accounting Standards ( SFAS ) No. 131, *Disclosures about Segments of an Enterprise and Related Information* ( SFAS 131 ). SFAS 131 establishes standards for reporting financial and descriptive information regarding operating segments. SFAS 131 also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions as to how to allocate resources and assess performance. The Company's chief operating decision maker, as defined under SFAS No. 131, is the chief executive officer. The Company believes it operates in one segment. All of the Company's revenues are generated in the United States and all of its assets are located in the United States.

**Significant Concentrations**

Two customers accounted for 92% and 67% of the total outstanding trade accounts receivable as of December 31, 2007 and 2006, respectively. Three customers accounted for approximately 91%, 83% and 86% of gross product sales during the years ended December 31, 2007, 2006 and 2005, respectively.

**Cash and Cash Equivalents**

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

The Company maintains cash deposits with federally insured banks that may at times exceed federally insured limits. As of December 31, 2007 and 2006, the Company had balances of approximately \$130,000 and \$5,000, respectively, in excess of federally insured limits.

**Marketable Security**

The Company recorded its investment in a marketable security in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* ( SFAS 115 ). The classification of securities is generally determined

at the date of purchase. The marketable security of the Company is classified as available-for-sale and reported at fair value with unrealized losses recognized net of tax in other comprehensive loss. Gains and losses on sales of investments in marketable securities, which are computed based on specific identification of the adjusted cost of each security, are included in investment income at the time of the sale.

The investment is in common stock of a U.S. publicly traded company owned by the Company that is classified as available-for-sale, included in current assets and reported at fair value with unrealized loss reported in 2006. The investment was received under the terms of an agreement and restricted from trading for one year from the acquisition date of September 8, 2006. The initial value of the investment was determined

## **CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

by taking a 15% discount from the market value to reflect trading restrictions. During 2007, the restriction on the investment in common stock was removed. As of December 31, 2007, a loss of approximately \$323,000 was recorded for the other-than-temporary impairment of the investment in accordance with SFAS 115, as management does not believe the value of these securities will be recovered.

#### **Accounts Receivable**

Accounts receivable are stated less an allowance for discounts of approximately \$81,000 as of December 31, 2007 and \$44,000 as of December 31, 2006. The Company's policy is to give its customers an early payment discount of 2%. The allowance for discounts is calculated as approximately 2% of outstanding invoices as of December 31, 2007 and 2006 because nearly all customers take advantage of these discounts. The Company sells its products to pharmaceutical distribution companies and retail organizations throughout the United States.

The Company performs ongoing credit evaluations and does not require collateral. As appropriate, the Company establishes provisions for potential credit losses. In the opinion of management, no allowance for doubtful accounts is necessary as of December 31, 2007 or 2006. The Company writes off accounts receivable when management determines they are uncollectible and credits payments subsequently received on such receivables to bad debt expense in the period received.

#### **Inventories**

Inventories consist of raw materials, work in process and finished goods. Raw materials include the active pharmaceutical ingredient ( API ) for a product to be manufactured, work in process includes the bulk inventory of tablets that are in the process of being packaged for sale and finished goods include pharmaceutical products ready for commercial sale or distribution as samples. Inventories are stated at the lower of cost or market value with cost determined under the first-in, first-out method. The Company's estimate of the net realizable value of its inventories is subject to judgment and estimation. The actual net realizable value of the Company's inventories could vary significantly from the Company's estimates and could have a material effect on the Company's financial condition and results of operations in any reporting period. In evaluating whether inventory is stated at the lower of cost or market, the Company considers such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. On a quarterly basis, the Company analyzes its inventory levels and writes down inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. As of December 31, 2007 and 2006, the Company established an allowance for obsolete inventory of approximately \$201,000 and \$100,000, respectively.

#### **Property and Equipment**

Property and equipment, stated at cost, are depreciated over the estimated useful lives of the assets ranging from three to seven years using the straight-line method. Leasehold improvements are amortized over the lesser of their estimated useful lives or the lives of the leases. Amortization expense for leasehold improvements has been included in depreciation expense in these consolidated financial statements. The useful lives of the assets are generally as follows:

Furniture and fixtures	5 to 7 years
Machinery and equipment	3 to 7 years
Computers and software	3 to 5 years
Leasehold improvements	5 to 7 years

F-60

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Maintenance and repairs that are not considered renewals or betterments are charged to expense as incurred. Upon sale or retirement, the cost of the assets and the related accumulated depreciation are removed from the respective property accounts and the resulting gain or loss, if any, is reflected in the consolidated statements of operations.

**Product Rights**

Product rights are capitalized as incurred and are amortized over the estimated useful life of the product or the remaining trademark or patent life, whichever is shorter, on a straight-line or other basis to match the economic benefit received. Amortization begins once FDA approval has been obtained and commercialization of the product begins. The Company evaluates its product rights annually to determine whether a revision to their useful lives should be made. This evaluation is based on management's projection of the future cash flows associated with the products.

**Impairment of Long-Lived Assets**

The Company evaluates the recoverability of its long-lived assets, including property and equipment and identifiable intangible assets, in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ( SFAS 144 ). SFAS 144 requires companies to perform impairment testing on an exception basis whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets is not recoverable.

Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. The Company did not record any impairment losses on long-lived assets in 2007, 2006 or 2005.

**Intellectual Property**

The Company's policy is to file patent and trademark applications to protect technology, inventions and improvements that are considered important to the development of its business. The patent and trademark positions of technology companies are uncertain and involve complex legal and factual questions for which important legal principles are largely unresolved. The Company accounts for its intellectual property under the guidance of SFAS No. 142, *Goodwill and Other Intangible Assets*. The costs associated with internally developed intellectual property, such as trademarks, are expensed as incurred.

**Revenue Recognition**

The Company's consolidated net revenues represent the Company's net product sales, royalty agreement revenues and collaboration agreement revenues. The following table sets forth the categories of the Company's net revenues (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
Gross product sales	\$ 31,258	\$ 24,596	\$ 23,521
Sales allowances	(5,011)	(4,157)	(7,903)

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Net product sales	26,247	20,439	15,618
Royalty agreement revenues	1,824	1,678	753
Collaboration agreement revenues			1,099
Net revenues	\$ 28,071	\$ 22,117	\$ 17,470

F-61

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Product Sales***

The Company recognizes revenue from its product sales in accordance with Securities and Exchange Commission Staff Accounting Bulletin ( SAB ) No. 104, *Revenue Recognition*, and SFAS No. 48, *Revenue Recognition When Right of Return Exists* ( SFAS 48 ), upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to pharmaceutical wholesalers, distributors and pharmacies, which have the right to return the products they purchase. Under SFAS 48, the Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns; estimated rebates in connection with contracts relating to managed care, Medicaid and Medicare; estimated chargebacks; price adjustments; product vouchers; co-pay vouchers; and prompt payment and other discounts.

The Company establishes revenue reserves on a product-by-product basis as its best estimate at the time of sale based on historical experience for each product adjusted to reflect known changes in the factors that impact such reserves. Reserves for chargebacks, rebates, vouchers and related allowances are established based upon contractual terms with customers; analysis of historical levels of discounts, chargebacks, rebates and voucher redemptions; communications with customers; purchased information about the rate of prescriptions being written and the levels of inventory remaining in the distribution channel; expectations about the market for each product; and anticipated introduction of competitive products.

Consistent with industry practice, the Company offers customers the ability to return products in the six months prior to, and the 12 months after, the products expire. The Company adjusts its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include its estimate of inventory levels of its products in the distribution channel, the shelf life of the product shipped, competitive issues such as new product entrants and other known changes in sales trends. The Company evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve accordingly.

The Company's estimates of product rebates and price adjustments are based on its estimated mix of sales to various third-party payors, which are entitled either contractually or statutorily to discounts from the Company's listed prices of its products. The Company makes these judgments based upon the facts and circumstances known to it in accordance with GAAP. In the event that the sales mix to third-party payors is different from its estimates, the Company may be required to pay higher or lower total rebates than it has estimated.

***Royalty Agreement Revenues***

The Company also receives royalties under license agreements with a number of third parties that sell products to which the Company has rights. The license agreements provide for the payment of royalties based on sales of the licensed product. These revenues are recorded based on estimates of the sales that occurred in the relevant period. The relevant period estimates of sales are based on interim data provided by the licensees and analysis of historical royalties paid, adjusted for any changes in facts and circumstances, as appropriate. The Company maintains regular communication with its licensees to gauge the reasonableness of its estimates. Differences between actual royalty agreement revenues and estimated royalty agreement revenues are reconciled and adjusted for in the period in which they become known, typically the following quarter.

***Collaboration Agreement Revenues***

The Company recognized collaboration agreement revenues as a result of a co-promotion agreement with Lupin Pharmaceuticals, Inc. ( Lupin Pharmaceuticals ). Revenues associated with this agreement were recognized based on the calculation of shared revenues using an agreed-upon average sales price that was

F-62

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

applied to the sales volume generated by the Company. The sales volume was based on an analysis of prescription-level data by assigned, targeted prescribers within the United States.

**Advertising**

Advertising expenses, which include promotional expenses and the cost of samples, are generally expensed as incurred. Advertising expenses related to new products are expensed upon the first public showing of the product. Advertising expenses were approximately \$2.2 million, \$967,000 and \$4.7 million for the years ended December 31, 2007, 2006 and 2005, respectively.

**Shipping and Handling Costs**

The Company includes shipping and handling costs within cost of product sales. Shipping and handling costs were approximately \$352,000, \$184,000 and \$271,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

**Stock-Based Compensation**

Prior to January 1, 2006, the Company accounted for stock-based awards to employees under the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and adopted the disclosure-only alternative of SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ). Under the intrinsic-value method, stock-based compensation expense is measured as the amount at which the fair value of the underlying stock at the date of grant exceeds the exercise price. Because the exercise price for options awarded to employees is equal to the fair value at the grant date, the Company did not recognize compensation expense for stock options granted to employees prior to 2006.

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123(R) (revised 2004), *Share-Based Payment* ( SFAS 123(R) ), using the prospective application method, which requires the Company to recognize compensation cost for new awards and awards modified, repurchased or cancelled on or after January 1, 2006. Awards outstanding at January 1, 2006 continue to be accounted for using the accounting principles originally applied to the award. The expense associated with stock-based compensation is recognized on a straight-line basis over the service period of each award.

For the year ended December 31, 2005, if the Company had determined employee compensation expense based on the fair value at the date of grant consistent with SFAS 123, the Company's pro forma net loss would have been as follows (in thousands):

Net loss, as reported	\$ (11,438)
Deduct: Total compensation expense for employee stock options, as determined under the fair value based method for all awards	(2)
Net loss, pro forma	\$ (11,440)

Stock-based compensation granted to non-employees is accounted for in accordance with SFAS 123(R) and Emerging Issues Task Force ( EITF ) Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, which requires that compensation be recorded each reporting period for changes in the fair value of the Company's stock until the measurement date. The measurement date is generally considered to be the date when all services have been rendered or the date that options are fully vested.

During 2007, 2006 and 2005, the Company recorded approximately \$290,000, \$76,000 and \$0 in employee stock-based compensation expense and \$3,000, \$1,200 and \$4,000 in non-employee stock-based compensation expense, respectively.

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Determining the appropriate fair value model and the related assumptions requires judgment. The fair value of each option grant is estimated using the Black-Scholes-Merton option-pricing model on the date of grant as follows:

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
Estimated dividend yield	0.00%	0.00%	0.00%
Expected stock price volatility	68.00%	67.00%	75.00%
Risk-free interest rate	3.52 - 4.79	4.28 - 4.30	3.84 - 4.06
Expected life of option (in years)	6.04	5	10
Weighted-average fair value per share	\$0.30	\$0.06	\$0.07

The expected volatility rates are estimated based on the actual volatility of comparable public companies over the expected life. The expected life represents the average time that options that vest are expected to be outstanding. The expected life of employee stock options is based on the mid-point between the vesting date and the contractual term in accordance with the simplified method prescribed in SAB No. 107, *Share-Based Payment*, and the expected life for stock-based compensation granted to non-employees is the contractual life. The risk-free rate is based on the U.S. Treasury yield curve during the expected life of the option.

**Other Charges**

Other charges consist of the following (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
Settlement expenses (see Note 12)	\$ 245	\$ 1,679	
Foregone merger costs (see Note 12)		240	
Forfeiture of product rights (see Note 2 - Product Rights)		1,662	\$ 1,000
Other charges	\$ 245	\$ 3,581	\$ 1,000

**Income Taxes**

Deferred income tax assets and liabilities are computed annually for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

**Fair Value of Financial Instruments**

The carrying amount of the Company's cash and cash equivalents, receivables, accounts payable, line of credit and license agreement liability approximate their fair values at December 31, 2007 and 2006.

**New Accounting Pronouncements**

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( SFAS 162 ). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP (the GAAP hierarchy ). SFAS 162 makes the GAAP hierarchy explicitly and directly applicable to preparers of financial statements, a step that recognizes preparers' responsibilities for

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

selecting the accounting principles for their financial statements, and sets the stage for making the framework of FASB Concept Statements fully authoritative. The effective date for SFAS 162 is 60 days following the SEC's approval of the Public Company Accounting Oversight Board's related amendments to remove the GAAP hierarchy from auditing standards, where it has resided for some time. The Company does not expect the adoption of SFAS 162 to have a material impact on its financial statements.

In April 2008, the FASB issued FASB Staff Position Financial Accounting Standard 142-3, *Determination of the Useful Life of Intangible Assets* ( FSP FAS 142-3 ). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, *Goodwill and Other Intangible Assets*. In developing assumptions about renewal or extension, FSP FAS 142-3 requires an entity to consider its own historical experience or, if it has no experience, market participant assumptions, adjusted for the entity-specific factors in paragraph 11 of SFAS 142. FSP FAS 142-3 expands the disclosure requirements of SFAS 142 and is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, with early adoption prohibited. The guidance for determining the useful life of a recognized intangible asset must be applied prospectively to intangible assets acquired after the effective date. The disclosure requirements must be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. The Company does not expect the adoption of FSP FAS 142-3 to have a material impact on its financial statements.

In November 2007, the EITF issued EITF Issue No. 07-01, *Accounting for Collaborative Arrangements* ( EITF 07-01 ). EITF 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from or made to other collaborators based on other applicable generally accepted accounting principles or, in the absence of other applicable generally accepted accounting principles, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of EITF 07-01 to have a material impact on its financial statements.

In June 2007, the EITF issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payments should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The initial adjustment to reflect the effect of applying this EITF as a change in accounting principle is accounted for as a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. The adoption of EITF 07-03 did not have a material impact on the Company's financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* ( SFAS 141(R) ). SFAS 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values and changes other practices under SFAS No. 141, *Business Combinations*, some of which could have a material impact on how an entity accounts for its business combinations. SFAS 141(R) also requires additional disclosure of information surrounding a business combination so that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008 and is applied prospectively to business combinations for which

the acquisition date is on or after January 1, 2009. The provisions of SFAS 141(R) will only impact the Company's financial statements if the Company is a party to a business combination after the effective date of the pronouncement.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interest in Consolidated Financial Statements* an amendment of ARB No. 51 ( SFAS 160 ). SFAS 160 requires entities to report non-



**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

controlling minority interests in subsidiaries as equity in consolidated financial statements. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. SFAS 160 is applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for presentation and disclosure requirements, which are applied retrospectively for all periods presented. The Company does not expect the adoption of SFAS 160 to have a material impact on its financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of SFAS 115* ( SFAS 159 ). SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company's choice to use fair value on its earnings. It also requires companies to display the fair value of those assets and liabilities for which they have chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company was required to adopt SFAS 159 on January 1, 2008. The adoption of SFAS 159 did not have a material impact on the Company's financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ( SFAS 157 ). SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. In February 2008, the FASB issued FSP 157-2, which defers the effective date of applying the provisions of SFAS 157 to the fair value measurement of nonfinancial assets and nonfinancial liabilities until fiscal years beginning after November 15, 2008. The Company adopted the provisions of SFAS 157 that pertain to financial assets and liabilities on January 1, 2008. The adoption of SFAS 157 did not have a material impact on the Company's financial statements. The Company is currently evaluating the effect FSP 157-2 will have on its financial statements.

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109* ( FIN 48 ). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The adoption of FIN 48 did not have a material impact on the Company's financial statements.

**NOTE 2: BALANCE SHEET DATA****Accounts Receivable**

Accounts receivable consisted of the following as of December 31 (in thousands):

	2007	2006
Trade accounts receivable	\$ 3,585	\$ 1,843
Royalties receivable	998	175

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Other receivables	2,027	306
Total accounts receivable	6,610	2,324
Less allowance for discounts	(81)	(44)
Accounts receivable, net	\$ 6,529	\$ 2,280

F-66

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Inventories**

Inventories consisted of the following as of December 31 (thousands):

	<b>2007</b>	<b>2006</b>
Raw materials	\$ 1,564	\$ 468
Work in process	287	352
Finished goods:		
Pharmaceutical products trade	625	569
Pharmaceutical products samples	723	558
Total	3,199	1,947
Inventory allowances	(201)	(100)
Inventories, net	\$ 2,998	\$ 1,847

**Property and Equipment**

Property and equipment consisted of the following as of December 31 (in thousands):

	<b>2007</b>	<b>2006</b>
Computers and software	\$ 244	\$ 183
Machinery and equipment	6	6
Furniture and fixtures	114	112
Leasehold improvements	15	15
Total	379	316
Less accumulated depreciation	(170)	(99)
Property and equipment, net	\$ 209	\$ 217

Depreciation expense for the years ended December 31, 2007, 2006 and 2005 was approximately \$71,000, \$58,000 and \$52,000, respectively.

**Product Rights**

Product rights consisted of the following as of December 31 (in thousands):

	<b>2007</b>	<b>2006</b>
BALACET <sup>®</sup> product rights acquired from Vintage Pharmaceuticals, LLC ( Vintage )	\$ 7,549	\$ 7,549
SPECTRACEF <sup>®</sup> product rights acquired through entry into a license agreement with Meiji Seika Kaisha, Ltd. ( Meiji )	4,505	1,940
Technology rights acquired from Neos Therapeutics, L.P. ( Neos )	500	500
ALLERX <sup>®</sup> trademark acquired from Everton Pharmaceuticals, LLC ( Everton )	75	
Total	12,629	9,989
Less accumulated amortization	(7,693)	(4,533)
Product rights, net	\$ 4,936	\$ 5,456

F-67

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Amortization expense for the years ended December 31, 2007, 2006 and 2005 was approximately \$3.2 million, \$2.6 million and \$1.9 million, respectively. The Company is amortizing the BALACET product rights over an estimated useful life of three years, the SPECTRACEF product rights over an estimated useful life of nine years and the ALLERX trademark over an estimated useful life of four years. The Company expects to begin amortizing the rights acquired from Neos upon commercialization of the first product using these rights, expected to be in 2009, over an estimated useful life of 15 years.

Future estimated amortization expense (excluding the rights acquired from Neos) subsequent to December 31, 2007 is as follows (in thousands):

2008	\$ 1,067
2009	438
2010	437
2011	426
2012	420
Thereafter	1,648
	\$ 4,436

During the year ended December 31, 2006, the Company entered into a settlement with Lupin Ltd. (see Note 12) agreeing, among other things, to relinquish all rights to a product license acquired from Lupin Ltd. The forfeiture of the product rights of approximately \$1.7 million is included in other charges in the accompanying consolidated statements of operations.

During the year ended December 31, 2005, the Company entered into negotiations to purchase certain additional U.S. pharmaceutical product rights by signing a term sheet and making a \$1.0 million nonrefundable standstill payment. The payment allowed the Company to preserve and extend its rights to purchase a trademark that was to be used upon the launch of an extended-release cephalexin product. When this project was abandoned by the Company's management at the end of 2005, the trademark was no longer necessary, and the Company therefore forfeited the standstill payment. The forfeiture of the standstill payment is included in other charges in the accompanying consolidated statements of operations.

**Accrued Expenses**

Accrued expenses consisted of the following as of December 31 (in thousands):

	<b>2007</b>	<b>2006</b>
Accrued returns	\$ 4,913	\$ 5,781
Accrued rebates	303	140
Accrued other sales allowances	828	687

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Accrued compensation and benefits	1,596	1,318
Accrued royalties	1,940	484
Accrued interest, affiliate	1,490	549
Accrued interest	71	34
Accrued expenses, other	22	9
Accrued arbitration settlement expenses (see Note 12)		1,140
Total accrued expenses	\$ 11,163	\$ 10,142

F-68

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 3: LICENSE AGREEMENT LIABILITY**

On October 12, 2006, the Company entered into a license and supply agreement with Meiji granting the Company an exclusive, nonassignable U.S. license to manufacture and sell a 200 mg dosage of SPECTRACEF, using cefditoren pivoxil supplied by Meiji. In consideration for the license, the Company agreed to pay Meiji a nonrefundable license fee of \$6.0 million in six installments over a period of five years from the date of the agreement. The agreement provided that if a generic cefditoren product was launched in the United States prior to October 12, 2011, the Company would be released from its obligation to make any further license fee payments due after the date of launch. In 2006, the Company estimated that a generic active agreement would be available in two and a half years, which would limit the total installment payments to \$2.25 million.

On July 27, 2007, the Company entered into an amendment to the license and supply agreement and a letter agreement supplementing the license and supply agreement. The amendment to the license and supply agreement extended the Company's rights under the agreement to additional products and additional therapeutic indications of products containing cefditoren pivoxil supplied by Meiji that are jointly developed by Meiji and the Company and which Meiji and the Company agree to have covered by the agreement. The letter agreement provides that if the Company successfully launches a 400 mg product (SPECTRACEF 400 mg), a once-daily product (SPECTRACEF Once Daily) and/or a pediatric product (SPECTRACEF Suspension) and sales of these products substantially lessen the generic product's adverse effect on SPECTRACEF sales, the Company will be required to continue paying Meiji a reasonable amount of the license fee as mutually agreed by the parties. Therefore, in 2007, the Company revised its estimate of payments to include the full \$6.0 million in installments over five years since October 2006.

The license and supply agreement also requires the Company to make quarterly royalty payments based on the net sales of the cefditoren pivoxil products covered by the agreement. The Company is required to make these payments for a period of ten years from the date it launches a particular product.

The license agreement liability consists of the following as of December 31 (in thousands):

	<b>2007</b>	<b>2006</b>
License agreement liability to Meiji; imputed interest at 12% per annum; principal and interest payable for the remaining four years	\$ 3,535	\$ 1,690
Less current portion	(576)	(720)
Long-term	\$ 2,959	\$ 970

Principal maturities of the license agreement liability subsequent to December 31, 2007 are as follows (in thousands):

2008	\$ 576
2009	645
2010	972

2011	1,342
Total	\$ 3,535

**NOTE 4: LINE OF CREDIT**

In April 2005, the Company obtained financing under a bank line of credit for up to \$4.0 million, subject to a monthly borrowing base equal to 75% of accounts receivable balances outstanding 90 days or less and 50% of inventories. Interest is due monthly with all outstanding principal and interest due on maturity. The initial maturity of the line of credit was April 2006. The line of credit was modified in April 2006 to, among other

F-69

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

things, extend its maturity to April 2007. The line of credit was modified again in July 2007 to, among other things, extend its maturity to June 2008.

The line of credit requires the Carolina Note (as defined in Note 5) to be subordinated to the line of credit; the Company not incur any additional debt without the lender's consent; the Company's President and Chief Executive Officer to maintain a certain level of liquid assets in the Company; and the Company's President and Chief Executive Officer and Carolina Pharmaceuticals, Inc., an entity under common control with the Company, to jointly guarantee the line of credit. Amounts outstanding under the line of credit bear interest at a variable rate equal to the Wall Street Journal prime rate, which was 7.25% as of December 31, 2007. There was a \$1.75 million outstanding balance on and \$2.25 million of borrowing availability under the line of credit as of December 31, 2007 and 2006.

As of December 31, 2007, the line of credit was collateralized by the Company's accounts receivable, inventories, intangible assets and other personal property; a \$2.0 million deed of trust on the personal residence of the Company's President and Chief Executive Officer; and an assignment of deposits in the amount of \$1.0 million to the Company by the Company's President and Chief Executive Officer. The line of credit also required the Company's President and Chief Executive Officer to maintain at least a 48% ownership interest in the Company.

The Company was in violation of one of the covenants under the line of credit in 2005 and 2006. The bank waived these violations, and this covenant was removed from the line of credit in July 2007.

In June 2008, the Company modified the line of credit. The modification agreement extended the line of credit's maturity date to June 2009, required the Company's President and Chief Executive Officer to maintain a majority ownership in the Company and added Cornerstone BioPharma, Inc. and Aristos Pharmaceuticals, Inc. as joint guarantors of the line of credit. The modification agreement also revised the collateral for the line of credit to include assets held by Cornerstone BioPharma, Inc. and Aristos Pharmaceuticals, Inc. and reduced the \$1.0 million assignment of deposits from the Company's President and Chief Executive Officer to a \$500,000 assignment of deposits. Finally, the modification agreement revised the monthly borrowing base by eliminating the inventory component of the borrowing base and including in the borrowing base accounts receivable held by Cornerstone BioPharma, Inc. and Aristos Pharmaceuticals, Inc. and the \$500,000 cash deposited by the Company's President and Chief Executive Officer.

**NOTE 5: NOTES PAYABLE**

**Carolina Note**

In April 2004, the Company executed a promissory note with Carolina Pharmaceuticals Ltd. (Carolina Pharmaceuticals), an entity under common control with the Company, to borrow up to \$15.0 million for five years with an annual interest rate of 10% (Carolina Note). The Company borrowed \$13.0 million under the Carolina Note in April 2004. In June 2006, the Company and Carolina Pharmaceuticals agreed to offset approximately \$3.6 million in principal and \$1.8 million in accrued interest outstanding under the Carolina Note against equal amounts due to the Company from a related party.

As of December 31, 2007 and 2006, approximately \$9.4 million in principal was outstanding under this agreement plus approximately \$1.5 million and \$549,000 in accrued interest, respectively. The outstanding principal and accrued

interest are due in 2009.

**Vintage Note**

In July 2004, the Company purchased the rights to two products from Vintage for an upfront payment of \$5.0 million, a note payable of \$3.0 million and ongoing quarterly royalty payments equal to a percentage of the products' net sales. The note, which was collateralized by the product rights purchased, had an interest rate

F-70

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

of 2.5% and was to be paid in two installments of \$1.5 million on January 15, 2005 and July 15, 2005. The Company imputed interest at a rate of 18%, which yielded an original issue discount of approximately \$450,000. This discount was amortized over the life of the note, beginning in July 2004. Amortization of the discount in 2005 was approximately \$330,000. The discount was fully amortized as of December 31, 2005.

In May 2005, the note was amended to extend the maturity date for the January 15, 2005 installment to August 1, 2005 and the July 15, 2005 maturity date to November 1, 2005. In November 2005, the note was further amended to extend the payment date for the November 1, 2005 installment of \$1.5 million to February 1, 2006 and to change the interest rate to 5.0% beginning November 1, 2005. The Company paid the note payable in full in February 2006.

**NOTE 6: STOCKHOLDERS DEFICIT**

As of December 31, 2007, 2006 and 2005, Cornerstone BioPharma Holdings, Inc. was authorized to issue 50,000,000 shares of common stock, par value \$0.0001. As of December 31, 2007, the Company had outstanding 24,926,150 shares of \$0.0001 par value common stock.

In May 2005, in connection with the corporate restructuring (the Restructuring ) of Cornerstone BioPharma Holdings, Inc., the common stockholders and the common stock option holders of an affiliated company, Cornerstone Biopharma Holdings, Ltd., with the exception of its chief executive officer, cancelled their shares of stock and stock options in that company. Cornerstone Biopharma Holdings, Ltd. cancelled the outstanding shares of its common stock except for the 13,450,000 shares held by its chief executive officer. Cornerstone Biopharma Holdings, Ltd. does not currently engage in any operating activities; it only engages in investment activities.

In connection with the Restructuring, on May 15, 2005, Cornerstone BioPharma Holdings, Inc. sold and issued 11,750,000 shares of its common stock, at a price of \$0.0001 per share, to those individuals and entities whose common shares of Cornerstone Biopharma Holdings, Ltd. had previously been cancelled. Persons whose shares in Cornerstone Biopharma Holdings, Ltd. were cancelled received an equal number of shares of common stock of Cornerstone BioPharma Holdings, Inc. In addition, Cornerstone Biopharma Holdings, Ltd. exchanged all of its shares of Cornerstone Biopharma, Ltd. and Cornerstone BioPharma, Inc. for 13,450,000 shares of Cornerstone BioPharma Holdings, Inc.

**Stock Issued to Directors**

Also in connection with the Restructuring in 2005, Cornerstone BioPharma Holdings, Inc. sold and issued 200,000 additional shares of its common stock at a price of \$0.0001 to two of its directors as compensation for their service on its board. The Company has included compensation expense of approximately \$20,000 for the value of these shares in excess of their purchase price.

**Restricted Common Stock**

The Company required certain employees to enter into restricted common stock agreements that would allow them to vest in their stock over time. The Company has the right to purchase the unvested portion of the restricted common stock on termination of employment for the original purchase price per share, which in management's opinion approximated fair value on the date of issuance. The stock vests 25% annually.



**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following summarizes the restricted stock activity for the years ended December 31, 2007, 2006 and 2005:

	<b>Number of Restricted Shares Outstanding</b>
Nonvested as of December 31, 2004	1,607,500
Vested	(401,875)
Redeemed	(375,000)
Nonvested as of December 31, 2005	1,205,625
Vested	(401,875)
Redeemed	(375,000)
Nonvested as of December 31, 2006	428,750
Vested	(214,375)
Redeemed	
Nonvested as of December 31, 2007	214,375

**Warrants to Purchase Common Stock**

In February 2006, the Company issued a warrant to purchase 15,000 shares of common stock at \$0.10 per share in exchange for services. The warrant was valued at \$1,500 and is exercisable for a ten-year period from the date of grant. The fair value of the warrant granted was estimated on the date of grant using the Black-Scholes-Merton pricing model with the following assumptions: dividend yield of 0%, expected volatility of 157%, risk-free interest rate of 4.51% and expected life of ten years.

In July 2004, Cornerstone Biopharma Holdings, Ltd. issued an option to purchase 5% of its common shares to a company owned by a former stockholder of an affiliated company in connection with a license agreement. The option had an exercise price of \$100,000, had an exercise period that extended through December 31, 2009 and was exercisable for such number of shares that would give the optionholder a 5% ownership interest in Cornerstone Biopharma Holdings, Ltd. s issued and outstanding shares following the exercise. The fair value of the option was approximately \$48,000. In connection with the Restructuring, in July 2006, the option was cancelled and replaced with a warrant exercisable on the same terms but for shares in the Company. The Company did not record any additional compensation expense in 2006 when it issued the warrant because the fair value of the warrant was the same as the fair value of the option that it replaced. In April 2007, the Company amended the warrant to, among other things, decrease its exercise price to \$50,000 and extend its exercise period through December 31, 2010. In 2007, in accordance with SFAS 123(R), the Company recorded approximately \$508,000 of compensation expense due to the amendment of the warrant.

In June 2005, the Company issued two warrants to purchase 10,000 shares each of common stock of at \$0.10 per share in exchange for services. The warrants were valued at \$1,615 and are exercisable for a ten-year period from the date of grant. The fair value of the warrants granted was estimated on the date of grant using the Black-Scholes-Merton pricing model with the following assumptions: dividend yield of 0%, expected volatility of 75%, risk-free interest rate of 3.91% and expected life of ten years.

**NOTE 7: STOCK OPTIONS**

In May 2005, the Company adopted the Cornerstone BioPharma Holdings, Inc. 2005 Stock Option Plan (the Old Stock Plan ), which provided for the award of stock options to purchase up to 10,000,000 shares of the Company s common stock to employees, directors and consultants of the Company. Initial awards were made under the Old Stock Plan that were not properly authorized by the Company s Board of Directors, which

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

determined to ratify the awards and replace them with awards under the Cornerstone BioPharma Holdings, Inc. 2005 Stock Incentive Plan (the New Stock Plan), which had been established by the Board of Directors and which provided for the granting of up to 10,000,000 stock options to employees, directors and consultants of the Company. At its December 23, 2005 meeting, the Board of Directors directed the officers of the Company to seek the agreement of awardees to cancel the grants under the Old Stock Plan and to replace such grants with stock options under the New Stock Plan. Thus, the Board of Directors intended to replace the Old Stock Plan with the New Stock Plan and to eliminate the available option pool under the Old Stock Plan. Despite the Board of Directors' intention to replace the Old Stock Plan, the Company did not secure the consent of all optionees to terminate the awards under the Old Stock Plan and stock options exercisable for an aggregate of 272,500 shares of common stock remained outstanding under the Old Stock Plan as of December 31, 2007. All stock option awards subsequent to the adoption of the New Stock Plan have been awarded under the New Stock Plan.

The Board of Directors shall determine the exercise price, term and dates of the exercise of all options at their grant date. The Board of Directors determines the fair market value of the common stock. Under the Old Stock Plan and the New Stock Plan, options become vested over variable periods and expire not more than ten years after the date of grant.

The following table summarizes the stock option activity for the years ended December 31, 2005, 2006 and 2007:

	<b>Available Option  Shares</b>	<b>Granted Options  Outstanding</b>	<b>Weighted- Average Exercise Price</b>
Exchanged in the Restructuring Adoption of 2005 Stock Incentive Plan	(1) 10,000,000	602,500(1) 0	\$ 0.16
Balance as of December 31, 2005	10,000,000	602,500	0.16
Granted	(2,855,531)	2,855,531	0.10
Exercised		(101,150)	0.10
Cancelled	488,659	(488,659)	0.12
Balance as of December 31, 2006	7,633,128	2,868,222	0.11
Granted	(4,767,500)	4,767,500	0.43
Cancelled	30,884	(30,884)	0.15
Balance as of December 31, 2007	2,896,512	7,604,838	\$ 0.31

(1) Option pool reduced from 10,000,000 shares to 602,500 shares which is the aggregate number of shares that had been granted under the Old Stock Plan prior to the Board of Directors' action creating the New Stock Plan on December 23, 2005.

As of December 31, 2007, the aggregate intrinsic value of options outstanding was \$1,327,528 and the aggregate intrinsic value of options exercisable was \$627,890. The intrinsic value of options exercised during the year ended December 31, 2006 was \$0. There were no options exercised during the years ended December 31, 2005 and 2007.

F-73

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes the stock options vested and expected to vest as of December 31, 2007:

	<b>Number of Options</b>	<b>Weighted-Average Remaining Contractual Life (In Years)</b>	<b>Weighted-Average Exercise Price</b>
Outstanding	7,604,838	8.79	\$ 0.31
Exercisable	1,707,387	8.02	0.11

The following table summarizes information about the Company's stock options as of December 31, 2007:

<b>Exercise Price</b>	<b>Options Outstanding</b>	<b>Weighted- Average Contractual Life (Years)</b>	<b>Options Exercisable</b>
\$0.10	2,677,338	8.06	1,569,637
0.25	165,000	7.50	136,250
0.42	4,536,500	9.21	1,500
0.48	226,000	9.80	
	7,604,838		1,707,387

As of December 31, 2007 and 2006, there was approximately \$654,000 and \$96,000 of total unrecognized compensation cost related to nonvested stock-based compensation arrangements, which is expected to be recognized over a weighted-average period of 3.06 and 2.92 years, respectively.

**NOTE 8: LEASES****Operating Leases**

The Company leases its facilities and certain equipment and automobiles under noncancelable operating leases expiring at various dates through 2010. Rent expense was approximately \$466,000, \$559,000 and \$486,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

Future minimum payments under non-cancelable operating leases with initial terms of one year or more consist of the following as of December 31, 2007 (in thousands):

2008	\$ 262
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2009	60
2010	11
Total minimum lease payments	\$ 333

**NOTE 9: EMPLOYEE BENEFIT PLANS**

In 2004, the Company implemented a defined benefit pension plan for certain employees. The plan required the Company to pay premiums on individual insurance contracts to fund the benefits provided by the plan. The plan assets were invested in life insurance policies in the names of each of the participants. The Company contributed approximately \$52,000 and \$194,000 to the plan for the years ended December 31, 2006 and 2005. In 2006, the plan was terminated and all of its assets were distributed.

In 2004, the Company implemented a profit-sharing plan that was subject to the provisions of the Employee Retirement Income Security Act of 1974. Participants of the defined benefit pension plan were not eligible to participate in the profit-sharing plan. The Company was required to fund the plan in an amount equal to 7.5% of the participant's compensation for the plan year. For the years ended December 31, 2006 and 2005, there were funding requirements of approximately \$82,000 and \$41,000, respectively. The Company terminated the

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

profit-sharing plan in 2006. As of December 31, 2006, the Company had not made any contributions to this plan. The Company accrued a liability of \$138,000 and \$23,000 as of December 31, 2006 and 2005, respectively, for the contributions. The Company paid \$138,000 in 2007 to settle the liability.

The Company established a qualified 401(k) plan, effective January 1, 2005, covering all employees who are least 21 years of age. The Company's employees may elect to make contributions to the plan within statutory and plan limits, and the Company may elect to make matching or voluntary contributions. As of December 31, 2007, the Company had not made any contributions to the 401(k) plan. The Company incurred approximately \$4,000, \$8,000 and \$2,000 of expenses related to the plan for the years ended December 31, 2007, 2006 and 2005, respectively.

**NOTE 10: INCOME TAXES**

As discussed in Note 1, the Company's consolidated financial statements include the accounts of Cornerstone BioPharma Holdings, Inc., Cornerstone BioPharma, Inc., Cornerstone Biopharma, Ltd., and Aristos Pharmaceuticals, Inc. Cornerstone Biopharma, Ltd. is an Anguilla international business company and was taxed as a foreign corporation for U.S. tax purposes in 2007 and 2006. Because Cornerstone Biopharma, Ltd. is not subject to income tax in Anguilla, the Company's consolidated financial statements do not include a provision for income taxes for this entity. Cornerstone Biopharma, Ltd.'s income would have been taxed to the owner of Cornerstone BioPharma Holdings, Inc. if Cornerstone Biopharma, Ltd. had issued dividends to Cornerstone BioPharma Holdings, Inc. or if Cornerstone BioPharma Holdings, Inc. had sold the stock of this subsidiary.

The provision for income taxes includes the following (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
Current:			
Federal	\$ 62	\$	\$
State	68		
Total	130		
Deferred:			
Federal			
State			
Total			
Total tax provision	\$ 130	\$	\$



**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31 are as follows (in thousands):

	<b>2007</b>	<b>2006</b>
Current:		
Deferred tax assets:		
Accounts receivable, net	\$ 31	\$ 16
Allowance for doubtful accounts		
Inventories, net	177	38
Accrued expenses	2,881	2,830
Valuation allowance	(3,089)	(2,884)
Total current deferred tax assets	\$	\$
	<b>2007</b>	<b>2006</b>
Noncurrent:		
Deferred tax assets:		
Tax loss carryforwards	\$ 656	\$ 1,548
Contribution carryforwards		36
Deferred compensation	203	12
Warrants		1
Product license rights, net	244	115
Organizational costs, net	2	4
Tax credits	62	
Valuation allowance	(1,143)	(1,691)
Total noncurrent deferred tax assets	24	25
Deferred tax liabilities:		
Property and equipment, net	24	25
Net deferred tax asset – noncurrent		
Total net deferred tax asset	\$	\$

Income taxes computed at the statutory federal income tax rate of 34% are reconciled to the provision for income taxes as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
United States federal tax at statutory rate	\$ 238	\$ (177)	\$ (3,880)
State taxes (net of federal benefit)	30	(19)	(428)
Nondeductible expenses	237	84	109
Carryback net operating losses to 2004			75
Other	(32)	(4)	
Increase in valuation allowance	(343)	116	4,124
Provision for income taxes	\$ 130	\$	\$

F-76

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

As of December 31, 2007, the Company has federal net operating loss carryforwards of approximately \$1.7 million that expire beginning in the year 2025 as well as state tax net economic loss carryforwards of approximately \$1.9 million that expire beginning in 2020. The Company recognized approximately \$820,000 in tax benefits in 2007 related to net operating loss carryforwards.

The Tax Reform Act of 1986 contains provisions that limit the Company's ability to utilize the net operating loss carryforwards in the case of certain events, including significant changes in ownership interests. If the Company's net operating loss carryforwards are limited and the Company has taxable income that exceeds the permissible yearly net operating loss carryforwards, the Company would incur a federal income tax liability even though net operating loss carryforwards would be available in future years.

**NOTE 11: RELATED PARTY TRANSACTIONS**

**Stockholders**

In 2005, the Company obtained legal services from a stockholder and former director of the Company in the amount of approximately \$88,000. No such services were obtained in 2006 or 2007.

During 2007, 2006 and 2005, the Company made advances to its President and Chief Executive Officer, who is also the Company's majority stockholder, of approximately \$615,000, \$1.1 million and \$946,000, respectively. The President and Chief Executive Officer repaid all 2005 advances by December 31, 2005. As of December 31, 2007 and 2006, unpaid advances were approximately \$648,000 and \$35,000, respectively, and are included in amounts due from related parties as of those dates.

The Company has certain agreements with its President and Chief Executive Officer that provide certain benefits related to a qualified termination or change of control, as defined by the agreements.

**Other Related Parties**

As of December 31, 2007 and 2006, the Company owes Carolina Pharmaceuticals approximately \$260,000 in accrued royalties related to the sale of Humibid® and DECONSAL®. This amount is included in accrued royalties as disclosed in Note 2. The Company paid \$750,000 to Carolina Pharmaceuticals for royalties in 2006. The Company did not pay any royalties to Carolina Pharmaceuticals in 2005 or 2007. The Company's President and Chief Executive Officer is a controlling stockholder of Carolina Pharmaceuticals.

In 2005, the Company purchased DECONSAL II inventory samples from Carolina Pharmaceuticals for approximately \$109,000. Accounts payable of \$0 and approximately \$49,000 related to this purchase were outstanding as of December 31, 2007 and 2006, respectively.

In May 2005, the Company licensed certain product rights to Auriga Laboratories, Inc. (Auriga), which is also owned in part and/or directed by some of the Company's stockholders. The effective date of the agreement is August 1, 2005.

The Company received a royalty ranging from 8% to 30% of net sales, depending on the level of net sales. The Company's royalty is not to exceed \$1.7 million on an annual basis. Auriga assumed responsibility for royalty payments to the previous owner of the product rights as of the effective date. In 2006, the royalty agreement with Auriga was amended to reduce the royalty rates from 30% to 5% of net sales in a specific calendar quarter. The amendment also provided for Auriga to issue the Company 200,000 shares of its common stock. The fair value of the stock, determined as the trading price on date of grant discounted 15% for lack of marketability due to a one-year lock up period, was approximately \$332,000. As discussed in Note 1, the Company included this amount in royalty agreement revenues.

F-77

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company recognized royalty agreement revenues under the agreements with Auriga of approximately \$58,000, \$552,000 and \$511,000 for the years ended December 31, 2007, 2006 and 2005, respectively. The Company recorded approximately \$56,000 in accounts payable as of December 31, 2007 due to returns processed against royalties in 2007. The Company recorded a royalty receivable under the agreement of approximately \$117,000 as of December 31, 2006, which is included in amounts due from related parties.

**NOTE 12: CONTRACTUAL AGREEMENTS AND OBLIGATIONS**

**Royalties**

The Company has contractual obligations to pay royalties to the former owners of certain product rights that have been acquired by or licensed to the Company. These royalties are based on a percentage of net sales of the particular licensed product.

In August 2006, the Company entered into an agreement with Pharmaceutical Innovations, LLC ( Pharmaceutical Innovations ) for an exclusive license to a U.S. patent and know-how to manufacture, package, market and distribute various day-night products. In exchange for these rights, the Company was required to pay Pharmaceutical Innovations a special royalty of 8.5% of initial net sales of day-night products up to a total of \$250,000. The Company paid this special royalty in 2006 and 2007. In addition, the Company is obligated to pay royalties based on a percentage of the products annual net sales. The royalty rate increases as the annual net sales increase. Minimum annual royalties are \$300,000 per year under this agreement during the life of the licensed patent based on the products currently marketed by the Company.

**Inventory Purchases**

The Company purchases inventory from pharmaceutical manufacturers. During the year ended December 31, 2007, one vendor accounted for 23% of the Company's inventory purchases. During the years ended December 31, 2006, and 2005, two vendors accounted for 22% and 25%, respectively, of the Company's inventory purchases. Three vendors accounted for 37% of the Company's accounts payable as of December 31, 2007. Two vendors accounted for 42% of the Company's accounts payable as of December 31, 2006.

The Company has entered into an agreement with Vintage to exclusively manufacture two prescription pain products acquired from Vintage for prices established by the agreement, subject to renegotiation at each anniversary date. The agreement expires in July 2009 and may be renewed for subsequent one-year terms.

In connection with the license agreement with Meiji as described in Note 3, the Company also entered into a supply agreement with Meiji to purchase minimum quantities of cefditoren pivoxil, the API in SPECTRACEF, exclusively from Meiji. Under this agreement, Cornerstone is required to purchase the minimum quantities of cefditoren pivoxil necessary to support targeted gross sales of SPECTRACEF after the SPECTRACEF product launch of \$8.0 million for year one, \$11.0 million for year two, \$13.0 million for year three, \$17.0 million for year four and \$24.0 million for year five. If the Company does not meet its minimum purchase requirement in a given year, the Company must pay Meiji an amount equal to 50% of the shortfall in that year. The Company expects to exceed the minimum purchase requirements.

In July 2007, the Company entered into a supply agreement with Bayer HealthCare, LLC ( Bayer ) to purchase minimum quantities of the bulk tablets for the ALLERX Dose Pack family of products from Bayer during calendar years 2008 and 2009. An additional one-time cost of up to \$135,000 will be due on December 31, 2009 if the Company fails to meet the minimum annual purchase requirement of 27.0 million tablets per year for 2008 and 2009. The Company expects to exceed the minimum purchase requirements.

As of December 31, 2007 and 2006, the Company had outstanding purchase commitments related to inventory totaling approximately \$2.8 million and \$392,000, respectively.

F-78

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Co-promotion Agreements**

In February 2006, the Company signed a co-promotion agreement with Ascend Therapeutics, Inc. ( Ascend ) to provide detailing of a product to a specific physician population. As compensation, the Company paid a fee for detailing the product equal to 50% of net sales. This agreement was terminated in March 2008.

In March 2007 and June 2007, the Company entered into co-promotion agreements with SJ Pharmaceuticals, LLC ( SJ Pharmaceuticals ) to co-promote two of the Company's product lines. Under these agreements, the Company pays SJ Pharmaceuticals fees based on a percentage of the net profits of the products sold above a specified baseline based upon prescriptions by assigned, targeted prescribers within assigned sales territories. These targeted prescribers are mutually agreed upon by the Company and SJ Pharmaceuticals prior to the start of each quarter.

In April 2007, the Company entered into a co-promotion agreement with Atley Pharmaceuticals, Inc. ( Atley Pharmaceuticals ) to co-promote a prescription pain product beginning July 1, 2007. Under the agreement, the Company pays Atley Pharmaceuticals fees based on a percentage of the net profits from sales of the product above a specified baseline within assigned sales territories.

Each of these co-promotion agreements is subject to sunset fees that require the Company to pay additional fees for up to one year in the event of certain defined terminations of the agreements.

**Sales and Marketing Agreement**

In September 2005, the Company entered into a sales and marketing agreement with Pliva, Inc. ( Pliva ). Under this agreement, the Company receives all revenues, less usual and customary discounts and a distribution fee to Pliva calculated as a percentage of net revenues that Pliva generates on sales of Propoxyphene-APAP 100-500. The current term of the agreement expires December 31, 2008. The Company has given Pliva notice that at the end of the current term the Company will terminate the agreement.

**Settlements**

***Lupin Pharmaceuticals, Inc. and Lupin Ltd.***

In January 2005, the Company entered into a co-promotion agreement with Lupin Pharmaceuticals. Under this agreement, the Company co-promoted Suprax<sup>®</sup>, an oral suspension of cefixime, an anti-infective, with a focus on primary care physicians. The term of this agreement was January 1, 2005 through December 31, 2005, unless terminated earlier.

In May 2005, the Company entered into a collaboration and license agreement with Lupin Ltd. Under the terms of the agreement, the Company was to license a cephalexin product for sale and distribution in the United States and Puerto Rico. The Company and Lupin Ltd. were to collaborate to direct regulatory development to seek approval of the product. All development expenses were to be shared between the parties up to an aggregate amount of \$6.0 million.

Upon obtaining FDA approval, Lupin Ltd. would manufacture and supply product to the Company at a specified price and would receive a royalty based on a percentage of revenues generated from sales. The Company was contractually

obligated to maintain a sales force of at least 200 people at the time of the launch. In addition, Lupin Ltd. had the right, but not the obligation, to co-promote the product within the pediatric market.

The Company was required to make payments in relation to the product license rights as follows: \$1.5 million paid in May 2005; \$1.5 million due by May 2006; \$1.5 million within 10 days after submission of an NDA for the product; \$6.0 million within ten days after FDA approval of the product. In addition, the Company issued Lupin Ltd. a warrant to purchase 1,746,405 shares of Cornerstone BioPharma Holdings, Inc. common

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

stock for \$0.01 per share. The warrant was valued at approximately \$163,000 and was exercisable anytime from the grant date for a period of ten years.

In February 2006, Lupin Pharmaceuticals notified the Company that it had terminated the co-promotion agreement due to the Company's failure to meet certain requirements under the agreement.

In May 2006 and July 2006 the Company filed requests for arbitration related to the collaboration and license agreement and the co-promotion agreement, respectively.

In December 2006, the Company settled these disputes with Lupin Ltd. and Lupin Pharmaceuticals. The settlement agreement required the Company to release all of its interests in Suprax, return any Lupin Ltd. work product or intellectual property relating to cephalexin and pay the sum of \$1.25 million to Lupin Ltd. in three installments within 180 days of the settlement. The Lupin Ltd. warrant was placed in escrow and was cancelled upon completion of the payments. Upon receipt of each payment, Lupin Ltd. released a portion of the total warrants issued. In 2007 and 2006, 1,164,270 and 582,135, respectively, common stock shares of this warrant were deemed to have been cancelled. The Company has valued the warrants repurchased under the settlement at \$547,000 and recorded that amount as a reduction of equity. The additional payment required of \$703,000 and legal fees of approximately \$505,000 have been included in costs and expenses in 2006 as other charges. As of December 31, 2006, \$800,000 remained to be paid. As discussed in Note 2, this amount is included in accrued expenses on the consolidated balance sheet as accrued arbitration settlement expenses. The Company paid this amount in full in 2007.

***Adams Respiratory Therapeutics, Inc.***

In October 2004, the Company was included as a defendant in litigation with a related party, Carolina Pharmaceuticals, Inc., by Adams Respiratory Therapeutics, Inc. ( Adams ) that alleged trademark infringement, false advertising and unfair competition claims and sought damages and injunctive relief. The Company vigorously defended these allegations and filed various counterclaims. In January 2005, Adams and the Company entered into an agreement under which in February 2005 the Company received all of the rights to the ALLERX products held by Adams and Adams received all of the rights to the Humibid family of products held by the Company. Additionally, the parties released each other from all claims and damages in the above mentioned lawsuit. The agreement required the Company to assume the financial responsibility for the first \$1.0 million of returned Humibid product that was sold by the Company prior to February 15, 2005 and returned to Adams during the 18-month period beginning February 15, 2005. The Company recorded \$1.0 million in accrued expenses in the consolidated balance sheets as of December 31, 2007 and 2006 for this Humibid liability.

The Company also had \$746,000 in accrued royalty expenses related to ALLERX sales as of December 31, 2007. Conversely, Adams was financially responsible for the first \$1.0 million of ALLERX product returns for the same 18-month period. The Company recorded approximately \$355,000 and \$331,000 in accounts receivable in the consolidated balance sheets as of December 31, 2007 and 2006, respectively. After the 18-month period or the \$1.0 million threshold is met, the agreement provided that the Company would have the responsibility for all ALLERX product returns whether sold by the Company or Adams and Adams would bear the same liability for Humibid products. In connection with this agreement, Adams is obligated to pay the Company a royalty ranging from 1% to 2% of net Humibid sales for a period of three years after February 15, 2005 with a minimum annual royalty of \$50,000. The Company has recorded \$100,000 and \$50,000 in accounts receivable in the consolidated balance sheets

as of December 31, 2007 and 2006, respectively, related to the minimum royalty.

In 2006, a major wholesaler indicated that it was in possession of a significant amount of Humibid prescription inventory. Adams filed a complaint alleging that the Company and Carolina Pharmaceuticals, Inc. did not disclose the outstanding inventory in accordance with the prior agreement and are therefore financially

F-80

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

responsible for the returns. The Company and Carolina Pharmaceuticals, Inc. believed they were not liable for these returns under the agreement and filed a counterclaim. Since all Humibid prescription products were sold by Carolina Pharmaceuticals, Inc., the Company did not accrue any amounts related to this claim.

In May 2008, the Company settled the dispute with Adams. The agreement provides that all parties to the settlement are to be released from all legal claims made prior to January 2008 and that the Company and Carolina Pharmaceuticals, Inc. shall pay to Reckitt Benckiser, Inc., the parent of Adams, \$1.5 million in three installments to be paid as follows: \$500,000 by June 20, 2008; \$500,000 by June 30, 2008; and \$500,000 by September 30, 2008. In exchange, the Company is released from all liabilities. The total net amount accrued on the Company's consolidated balance sheet as of December 31, 2007 was approximately \$1.3 million. As of June 30, 2008, the Company has paid \$1.0 million related to the settlement agreement. The Company expects to pay \$291,000 on September 30, 2008. Carolina Pharmaceuticals, Inc. will make the remaining payment of \$209,000.

***Others***

In November 2006, the Company filed a legal complaint against a pharmaceutical company, certain affiliates of the pharmaceutical company and the manufacturer of a product launched by the pharmaceutical company that the Company believed infringed upon the patent of one of its products. By January 2007, the disputes with all involved parties were settled. The terms of the settlements required the parties to admit and acknowledge that the claims of the patent are valid and enforceable and covenant that the parties will not infringe on the claims of the patent by making, using, selling or offering for sale any product that would infringe on the patent. The settlements provided that the Company pay the parties for the value of certain inventory on hand, which was destroyed. The Company accrued approximately \$256,000 in 2006 related to these potential inventory purchases. These amounts, in addition to the legal fees related to the settlement of approximately \$215,000, are included in the accompanying consolidated statements of operations as other charges in 2006. The total actual inventory payments made related to the settlement in 2007 amounted to approximately \$236,000, and the excess accrual of \$20,000 was reversed as of December 31, 2007.

In addition, as part of the settlement, the Company also committed to pay \$75,000 for trademark rights. The Company also made this payment in 2007.

In response to a claim of infringement filed by the Company in early 2008, a pharmaceutical company has filed a counterclaim that the patent, which is licensed to the Company, is invalid and moved to stay the litigation pending the re-examination of the Company's patent. No monetary relief has been requested in the counterclaim. The court granted defendants' motion and stayed the litigation pending the re-examination of the Company's patent in February 2008. Separately, the U.S. Patent and Trademark Office ordered a re-examination of the patent. Additionally, in June 2008, the pharmaceutical company requested that the U.S. Patent and Trademark Office re-examine a related second patent licensed to the Company by an affiliate of the licensor of the first patent, which is not at issue in the litigation. In concert with the licensor of the patents, the Company intends to vigorously pursue its claims and defend the counterclaim. The Company's intellectual property counsel has concluded that valid arguments exist for distinguishing the claims of the Company's patents over the references cited in the requests for re-examination. If the United States Patent and Trademark Office invalidates some or all of the claims under these patents, the Company could be exposed to increased generic competition relating to its various day-night products, and its future operating and financial results could be adversely affected. Because no monetary relief has been requested in the counterclaim, no amount has been accrued in these consolidated financial statements.

**Product Agreements**

In August 2006, the Company loaned Neos \$500,000 under a secured subordinated promissory note agreement. In December 2006, the Company entered into a product development agreement with Neos

F-81

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

providing the Company with an exclusive license to certain products under development utilizing Neos' s time release suspension technology. Under the terms of the agreement, the note with Neos was forgiven. The Company has recorded the \$500,000 consideration as product rights related to the time release suspension technology. The agreement requires Neos to develop each product at its own expense up to a defined milestone. After that milestone is achieved, the Company is required to reimburse Neos 110% of all direct costs incurred and pay \$150 per hour for personnel time incurred in the development of the products. The Company will also make milestone payments up to \$1.0 million for each product based on specific events. No development costs or milestone payments have been made or accrued as of December 31, 2007. Upon commercialization, the Company would also pay Neos royalties based on a percentage of net sales.

During 2007, the Company entered various research and development agreements. As of December 31, 2007, the Company had outstanding commitments related to ongoing research and development contracts totaling approximately \$312,000.

**Severance**

Selected executive employees of the Company have employment agreements which provide for severance payments ranging from three to 12 months of salary and benefits upon termination, depending on the reasons for the termination. The executive would also be required to execute a release and settlement agreement. No amount has been accrued for severance as of December 31, 2007 or 2006.

**Foregone Merger**

In June 2006, the Company was approached by a public company listed on the London Stock Exchange and offered the opportunity to merge with the public company. The Company pursued this opportunity until it was informed that the public company had been purchased, which resulted in the abandonment of the potential merger. Legal costs incurred in 2006 related to this opportunity of approximately \$240,000 have been included in the accompanying consolidated statement of operations.

**NOTE 13: SUBSEQUENT EVENTS**

**Development Agreements**

In February 2008, the Company entered into a development and manufacturing agreement requiring payment of \$250,000 to Neos and \$250,000 to Coating Place, Inc. ( Coating Place ) in relation to the development of a new product. The agreement includes licenses by Neos and Coating Place of their respective patent-pending technologies that are being used to develop the new product. After the product is launched, the parties will share net profits from sales of the product in equal parts.

In March 2008, the Company entered into a development, license and services agreement with Neos to license certain Neos patent-pending technology. Under the agreement, Neos will perform development work on a new product. The Company will pay hourly fees for the development work in addition to an aggregate of \$1.75 million in monthly fees from January 2008 through August 2008.

**Lease Agreement**

In May 2008, the Company entered into a lease agreement for a new corporate headquarters, which will occupy approximately 14,900 square feet of office space and is located in the Crescent Lakeside office complex, in Cary, North Carolina. The lease has an initial term that commences in December 2008 and expires in March 2016. Initial annual base rent under the lease is approximately \$350,000 with annual rent increases of approximately 3%. The Company also has an option to renew the lease for an additional five-year term through March 2021.

F-82

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Proposed Merger with Critical Therapeutics, Inc.**

On May 1, 2008, the Company and Critical Therapeutics, Inc. ( Critical Therapeutics ) entered into a merger agreement pursuant to which Neptune Acquisition Corp., a wholly owned subsidiary of Critical Therapeutics, will merge with and into the Company (the Merger ), with the Company continuing after the merger as the surviving company and a wholly owned subsidiary of Critical Therapeutics (the Merger Agreement ). If the Merger is completed, at the effective time of the Merger, all outstanding shares of the Company 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 the Company s common stock will be assumed by Critical Therapeutics and become options and warrants to purchase Critical Therapeutics common stock. The Merger Agreement provides that, at the effective time of the Merger, Critical Therapeutics will issue to the Company s stockholders, and assume the Company s 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 contemplated reverse stock split of Critical Therapeutics common stock to occur in connection with the Merger. Immediately following the effective time of the Merger, the Company s stockholders will own approximately 70%, and Critical Therapeutics stockholders will own approximately 30%, of Critical Therapeutics common stock, after giving effect to shares issuable pursuant to the Company s outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics outstanding options and warrants. The exchange ratio per share of the Company s common stock will be based on the number of shares of the Company s common stock outstanding on a fully diluted basis immediately prior to the effective time of the Merger and will not be determined until that time.

The consummation of the Merger is subject to a number of closing conditions, including the approval of both the Company s stockholders and Critical Therapeutics stockholders, approval by The NASDAQ Stock Market LLC of Critical Therapeutics application for re-listing of its common stock in connection with the Merger, the continued availability of its products and other customary closing conditions. As a condition to the Merger, Carolina Pharmaceuticals 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 shares of the Company s common stock prior to the effective time of the merger. The Company is targeting a closing of the transaction in the fourth quarter of 2008.

Immediately prior to the effective time of the Merger, Critical Therapeutics has agreed to effect a reverse stock split of its common stock whereby each issued and outstanding share of its common stock will be reclassified and combined into a fractional number of shares of common stock. The reverse stock split ratio is to be mutually agreed upon by the Company and 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 the initial listing standards for The NASDAQ Capital Market.

The Merger Agreement provides for the payment of a termination fee of \$1.0 million by each of the Company and Critical Therapeutics 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 the Company for up to \$150,000 in expenses and the Company has agreed to reimburse Critical Therapeutics for up to \$100,000 in expenses.

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 14: QUARTERLY FINANCIAL DATA (UNAUDITED)****Quarterly Financial Data (Unaudited)**

The following table summarizes selected unaudited condensed quarterly financial information for 2007 and 2006. The Company believes that all adjustments, consisting of normal recurring adjustments considered necessary for a fair presentation, have been included in the selected quarterly information (in thousands).

	<b>Quarter Ended December 31,</b>	<b>Quarter Ended September 30, (In thousands) (Unaudited)</b>	<b>Quarter Ended June 30,</b>	<b>Quarter Ended March 31,</b>
<b>2007</b>				
Net revenues	\$ 5,966	\$ 7,902	\$ 5,515	\$ 8,688
Total operating expenses	6,853	6,770	6,168	5,839
Operating (loss) income	(887)	1,132	(653)	2,849
Other expenses	(716)	(368)	(317)	(340)
(Loss) income before income taxes	(1,603)	764	(970)	2,509
Income taxes	551	(147)	98	(632)
Net (loss) income	\$ (1,052)	\$ 617	\$ (872)	\$ 1,877
<b>2006</b>				
Net revenues	\$ 3,963	\$ 8,571	\$ 3,535	\$ 6,048
Total operating expenses	7,200	5,015	4,368	4,564
Operating (loss) income	(3,237)	3,556	(833)	1,484
Other expenses	(321)	(291)	(290)	(373)
Net (loss) income	\$ (3,558)	\$ 3,265	\$ (1,123)	\$ 1,111

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

	<b>March 31, 2008 (Unaudited)</b>	<b>December 31, 2007 (Audited)</b>
	<b>(In thousands, except share and per share data)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 416	\$ 241
Marketable security	8	8
Accounts receivable, net	5,905	6,529
Amounts due from related parties	652	648
Inventories, net	3,855	2,998
Prepaid expenses	447	278
Total current assets	11,283	10,702
Property and equipment, net	205	209
Other assets:		
Product rights, net	5,198	4,936
Amounts due from related parties	38	29
Deposits	22	33
Total other assets	5,258	4,998
Total assets	\$ 16,746	\$ 15,909
<b>Liabilities</b>		
Current liabilities:		
Accounts payable	\$ 2,210	\$ 2,214
Accrued expenses	11,972	11,163
Current portion of license agreement liability	576	576
Line of credit	750	1,750
Income taxes payable	409	130
Total current liabilities	15,917	15,833
Long-term liabilities:		
License agreement liability, less current portion	2,959	2,959
Note payable, related party	9,412	9,412

Total long-term liabilities	12,371	12,371
Total liabilities	28,288	28,204
<b>Stockholders deficit</b>		
Common stock \$0.0001 par value, 50,000,000 shares authorized 24,926,150 shares issued and outstanding	2	2
Additional paid-in capital	885	801
Accumulated deficit	(12,429)	(13,098)
Total stockholders deficit	(11,542)	(12,295)
Total liabilities and stockholders deficit	\$ 16,746	\$ 15,909

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(Unaudited)</b>	
	<b>(In thousands)</b>	
Net revenues	\$ 9,445	\$ 8,688
Costs and expenses:		
Cost of product sales	565	668
Sales and marketing	3,908	2,053
Royalties	1,245	1,180
General and administrative	1,504	982
Research and development	98	5
Amortization and depreciation	758	842
Other charges		109
Total costs and expenses	8,078	5,839
Income from operations	1,367	2,849
Other expenses:		
Interest expense, net	(379)	(340)
Total other expenses	(379)	(340)
Income before income taxes	988	2,509
Provision for income taxes	319	632
Net income	\$ 669	\$ 1,877

## CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(Unaudited)</b>	
	<b>(In thousands)</b>	
<b>Cash flows from operating activities</b>		
Net income	669	1,877
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization and depreciation	758	842
Issuance of common stock warrants and options for services	84	49
Changes in operating assets and liabilities:		
Accounts receivable, net	624	(3,560)
Amounts due from related parties		4
Inventories, net	(857)	121
Prepaid expenses	(169)	(393)
Accounts payable	(4)	(57)
Accrued expenses	809	657
Income taxes payable	279	632
Net cash provided by operating activities	2,193	172
<b>Cash flows from investing activities</b>		
Advances to related parties	(13)	(405)
Proceeds from collection of advances to related parties		200
Purchase of property and equipment	(16)	
Purchase of product rights	(1,000)	(75)
Collection of deposits	11	
Net cash used in investing activities	(1,018)	(280)
<b>Cash flows from financing activities</b>		
Proceeds from line of credit	\$ 4,000	\$ 2,550
Principal payments on line of credit	(5,000)	(2,000)
Net cash (used in) provided by financing activities	(1,000)	550
Net increase (decrease) in cash and cash equivalents	175	442
<b>Cash and cash equivalents as of beginning of period</b>	<b>241</b>	<b>116</b>
<b>Cash and cash equivalents as of end of period</b>	<b>\$ 416</b>	<b>\$ 558</b>



**Supplemental disclosure of cash flow information**

Cash paid during the period for interest	\$	37	\$	53
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F-87

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**NOTE 1: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Nature of Operations**

Cornerstone BioPharma Holdings, Inc., together with its subsidiaries (collectively, the Company), is a specialty pharmaceutical company focused on acquiring, developing and commercializing prescription products for the respiratory market. The Company'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.

**Business Risk and Liquidity**

The Company's consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. From inception in 2004 through 2006, the Company incurred operating losses, including net losses of \$305,000 in 2006 and \$11.4 million in 2005. The Company's net income was approximately \$669,000 in the quarter ended March 31, 2008 and \$570,000 in the year ended December 31, 2007. As of March 31, 2008, Cornerstone's accumulated deficit was \$12.4 million.

The Company expects to continue to incur significant development and commercialization expenses as it advances the development of its product candidates; seeks regulatory approvals for its product candidates that successfully complete clinical testing; and expands its sales team and marketing capabilities to prepare for the commercial launch of future products, subject to approval by the U.S. Food and Drug Administration (FDA). The Company also expects to incur additional expenses to add operational, financial and management information systems and personnel, including personnel to support its product development efforts. Accordingly, the Company will need to increase its revenues to be able to sustain and increase its profitability on an annual and quarterly basis. There is no assurance that the Company will be able to do so. The Company's failure to achieve consistent profitability could impair its ability to raise capital, expand its business, diversify its product offerings and continue its operations.

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

As of March 31, 2008, the Company had approximately \$416,000 of cash and cash equivalents on hand and borrowing availability of approximately \$3.25 million under its line of credit. Based on its current operating plans, the Company believes that its existing cash and cash equivalents, revenues from product sales and borrowing availability under the 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. However, lower than projected cash flows as a result of reduced net product sales or increased expenses could require the Company to raise additional

capital in order to sustain its operations. There can be no assurance that management's plan will be executed as anticipated.

F-88

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)****Basis of Presentation**

The accompanying unaudited consolidated financial statements include the accounts of Cornerstone BioPharma Holdings, Inc. and its wholly owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the United States of America ( GAAP ) for interim financial information and with Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The Company believes that all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation, have been included. The unaudited consolidated financial statements should be read in conjunction with Cornerstone's Management's Discussion and Analysis of Financial Condition and Results of Operations and the Company's consolidated audited financial statements, including related notes, which are included in this proxy statement/prospectus.

Operating results for the three-month periods ended March 31, 2008 and 2007 are not necessarily indicative of the results for the full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in the Company's consolidated financial statements include certain judgments regarding revenue recognition, product rights, inventory valuation, accrued expenses and stock-based compensation.

**Revenue Recognition**

The Company's consolidated net revenues include net product sales and royalty agreement revenues. The following table sets forth the categories of the Company's net revenues for the three months ended March 31, 2008 and 2007, respectively (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
Gross product sales	\$ 10,470	\$ 9,642
Sales allowances	(1,470)	(1,426)
Net product sales	9,000	8,216
Royalty agreement revenues	445	472
Net revenues	\$ 9,445	\$ 8,688

**Product Sales**

The Company recognizes revenue from its product sales in accordance with Securities and Exchange Commission Staff Accounting Bulletin ( SAB ) No. 104, *Revenue Recognition*, and SFAS No. 48, *Revenue Recognition When Right of Return Exists* ( SFAS 48 ), upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to pharmaceutical wholesalers, distributors and pharmacies, which have the right to return the products they purchase. Under SFAS 48, the Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns; estimated rebates in connection with contracts relating to managed care, Medicaid and Medicare; estimated chargebacks; price adjustments; product vouchers; co-pay vouchers; and prompt payment and other discounts.

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

The Company establishes revenue reserves on a product-by-product basis as its best estimate at the time of sale based on historical experience for each product adjusted to reflect known changes in the factors that impact such reserves. Reserves for chargebacks, rebates, vouchers and related allowances are established based upon contractual terms with customers; analysis of historical levels of discounts, chargebacks, rebates and voucher redemptions; communications with customers; purchased information about the rate of prescriptions being written and the levels of inventory remaining in the distribution channel; expectations about the market for each product; and anticipated introduction of competitive products.

Consistent with industry practice, the Company offers customers the ability to return products in the six months prior to, and the 12 months after, the products expire. The Company adjusts its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include its estimate of inventory levels of its products in the distribution channel, the shelf life of the product shipped, competitive issues such as new product entrants and other known changes in sales trends. The Company evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve accordingly.

The Company's estimates of product rebates and price adjustments are based on its estimated mix of sales to various third-party payors, which are entitled either contractually or statutorily to discounts from the Company's listed prices of its products. The Company makes these judgments based upon the facts and circumstances known to it in accordance with GAAP. In the event that the sales mix to third-party payors is different from its estimates, the Company may be required to pay higher or lower total rebates than it has estimated.

***Royalty Agreement Revenues***

The Company also receives royalties under license agreements with a number of third parties that sell products to which the Company has rights. The license agreements provide for the payment of royalties based on sales of the licensed product. These revenues are recorded based on estimates of the sales that occurred in the relevant period. The relevant period estimates of sales are based on interim data provided by the licensees and analysis of historical royalties paid, adjusted for any changes in facts and circumstances, as appropriate. The Company maintains regular communication with its licensees to gauge the reasonableness of its estimates. Differences between actual royalty agreement revenues and estimated royalty agreement revenues are reconciled and adjusted for in the period in which they become known, typically the following quarter.

**New Accounting Pronouncements**

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( SFAS 162 ). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP (the GAAP hierarchy ). SFAS 162 makes the GAAP hierarchy explicitly and directly applicable to preparers of financial statements, a step that recognizes preparers' responsibilities for selecting the accounting principles for their financial statements, and sets the stage for making the framework of FASB Concept Statements fully authoritative. The effective date for SFAS 162 is 60 days following the SEC's approval of the Public Company Accounting Oversight Board's related amendments to remove the GAAP hierarchy from auditing standards, where it has resided for some time. The Company does not expect the adoption of SFAS 162 to have a material impact on its financial

statements.

In April 2008, the FASB issued FASB Staff Position Financial Accounting Standard 142-3, *Determination of the Useful Life of Intangible Assets* ( FSP FAS 142-3 ). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, *Goodwill and Other Intangible Assets*. In developing assumptions about

F-90

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

renewal or extension, FSP FAS 142-3 requires an entity to consider its own historical experience or, if it has no experience, market participant assumptions, adjusted for the entity-specific factors in paragraph 11 of SFAS 142. FSP FAS 142-3 expands the disclosure requirements of SFAS 142 and is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, with early adoption prohibited. The guidance for determining the useful life of a recognized intangible asset must be applied prospectively to intangible assets acquired after the effective date. The disclosure requirements must be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. The Company does not expect the adoption of FSP FAS 142-3 to have a material impact on its financial statements.

In November 2007, the FASB's Emerging Issues Task Force (EITF) issued EITF Issue No. 07-01, *Accounting for Collaborative Arrangements* (EITF 07-01). EITF 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from or made to other collaborators based on other applicable generally accepted accounting principles or, in the absence of other applicable generally accepted accounting principles, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of EITF 07-01 to have a material impact on its financial statements.

In June 2007, the EITF issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payments should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The initial adjustment to reflect the effect of applying this EITF as a change in accounting principle is accounted for as a cumulative-effect adjustment to retained earnings as of the beginning of the year of adoption. The adoption of EITF 07-03 did not have a material impact on the Company's financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS 141(R)). SFAS 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values and changes other practices under SFAS No. 141, *Business Combinations*, some of which could have a material impact on how an entity accounts for its business combinations. SFAS 141(R) also requires additional disclosure of information surrounding a business combination so that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008 and is applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009. The provisions of SFAS 141(R) will only impact the Company's financial statements if the Company is a party to a business combination after the effective date of the pronouncement.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interest in Consolidated Financial Statements - an amendment of ARB No. 51* (SFAS 160). SFAS 160 requires entities to report non-controlling minority interests in subsidiaries as equity in consolidated financial statements. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. SFAS 160 is applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for presentation and disclosure requirements, which are applied retrospectively for all periods presented. The Company does not expect the adoption of SFAS 160 to have a material impact on its financial



statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of SFAS 115* ( SFAS 159 ). SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and

F-91

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company's choice to use fair value on its earnings. It also requires companies to display the fair value of those assets and liabilities for which they have chosen to use fair value on the face of the balance sheet. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company was required to adopt SFAS 159 on January 1, 2008. The adoption of SFAS 159 did not have a material impact on the Company's financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ( SFAS 157 ). SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. In February 2008, the FASB issued FSP 157-2, which defers the effective date of applying the provisions of SFAS 157 to the fair value measurement of nonfinancial assets and nonfinancial liabilities until fiscal years beginning after November 15, 2008. The Company adopted the provisions of SFAS 157 that pertain to financial assets and liabilities on January 1, 2008. The adoption of SFAS 157 did not have a material impact on the Company's financial statements. The Company is currently evaluating the effect FSP 157-2 will have on its financial statements.

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* — an interpretation of FASB Statement No. 109 ( FIN 48 ). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The adoption of FIN 48 did not have a material impact on the Company's financial statements.

**NOTE 2: BALANCE SHEET**

**Inventories**

Inventories are stated at the lower of cost or market value with cost determined under the first-in, first-out method. As of March 31, 2008, the Company held \$3.9 million of inventory. On a quarterly basis, the Company analyzes its inventory levels and writes down inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected requirements based upon anticipated product revenues. As of March 31, 2008 and December 31, 2007, the Company established an allowance for obsolete inventory of approximately \$168,000 and \$201,000, respectively.

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

Inventories consisted of the following as of March 31, 2008 and December 31, 2007 (in thousands):

	<b>March 31, 2008</b>	<b>December 31, 2007</b>
Raw materials	\$ 496	\$ 1,564
Work in process	1,214	287
Finished goods:		
Pharmaceutical products trade	1,776	625
Pharmaceutical products samples	537	723
Total	4,023	3,199
Inventory allowances	(168)	(201)
Inventories, net	\$ 3,855	\$ 2,998

**Property and Equipment**

Property and equipment consisted of the following as of March 31, 2008 and December 31, 2007 (in thousands):

	<b>March 31, 2008</b>	<b>December 31, 2007</b>
Computers and software	\$ 250	\$ 244
Machinery and equipment	6	6
Furniture and fixtures	124	114
Leasehold improvements	15	15
Total	395	379
Less accumulated depreciation	(190)	(170)
Property and equipment, net	\$ 205	\$ 209

Depreciation expense for the quarters ended March 31, 2008 and 2007 was approximately \$20,000 and \$16,000, respectively.

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)****Product Rights**

Product rights consisted of the following as of March 31, 2008 and December 31, 2007 (in thousands):

	<b>March 31, 2008</b>	<b>December 31, 2007</b>
BALACET® product rights acquired from Vintage Pharmaceuticals, LLC ( Vintage )	\$ 7,549	\$ 7,549
SPECTRACEF® product rights acquired through entry into a license agreement with Meiji Seika Kaisha, Ltd. ( Meiji )	4,505	4,505
Technology rights acquired from Neos Therapeutics, L.P. ( Neos )	500	500
Product rights acquired from Coating Place, Inc. ( Coating Place ) and Neos	1,000	
ALLERX® trademark acquired from Everton Pharmaceuticals, LLC ( Everton )	75	75
 Total	 13,629	 12,629
Less accumulated amortization	(8,431)	(7,693)
 Product rights, net	 \$ 5,198	 \$ 4,936

Amortization expense for the quarters ended March 31, 2008 and 2007 was approximately \$738,000 and \$826,000, respectively. The Company is amortizing the BALACET product rights over an estimated useful life of three years, the SPECTRACEF product rights over an estimated useful life of nine years and the ALLERX trademark over an estimated useful life of four years. The Company expects to begin amortizing the rights acquired from Neos and Coating Place upon commercialization of the first product using these rights, expected to be in 2009, over an estimated useful life of 15 years.

Future estimated amortization expense (excluding the rights acquired from Neos and Coating Place) subsequent to March 31, 2008 is as follows (in thousands):

2008	\$ 328
2009	438
2010	437
2011	426
2012	420
Thereafter	1,649
	 \$ 3,698



**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)  
(Unaudited)****Accrued Expenses**

Accrued expenses consisted of the following as of March 31, 2008 and December 31, 2007:

	<b>March 31, 2008</b>	<b>December 31, 2007</b>
Accrued returns	\$ 5,455	\$ 4,913
Accrued rebates	207	303
Accrued other sales allowances	804	828
Accrued compensation and benefits	1,001	1,596
Accrued royalties	2,581	1,940
Accrued interest, affiliate	1,726	1,490
Accrued interest	175	71
Accrued expenses, other	23	22
Total accrued expenses	\$ 11,972	\$ 11,163

**NOTE 3: LINE OF CREDIT**

The Company has financing under a bank line of credit for up to \$4.0 million, subject to a monthly borrowing base equal to 75% of accounts receivable balances outstanding 90 days or less and, until June 2008, 50% of inventories. Interest is due monthly with all outstanding principal and interest due on maturity. Amounts outstanding under the line of credit bear interest at a variable rate equal to the Wall Street Journal prime rate, which was 5.25% as of March 31, 2008. There was a \$750,000 outstanding balance on and \$3.25 million of borrowing availability under the line of credit as of March 31, 2008.

In June 2008, the Company modified the line of credit. The modification agreement extended the line of credit's maturity date to June 2009, required the Company's President and Chief Executive Officer to maintain a majority ownership in the Company and added Cornerstone BioPharma, Inc. and Aristos Pharmaceuticals, Inc. as joint guarantors of the line of credit. The modification agreement also revised the collateral for the line of credit to include assets held by Cornerstone BioPharma, Inc. and Aristos Pharmaceuticals, Inc. and reduced the \$1.0 million assignment of deposits from the Company's President and Chief Executive Officer to a \$500,000 assignment of deposits. Finally, the modification agreement revised the monthly borrowing base by eliminating the inventory component of the borrowing base and including in the borrowing base accounts receivable held by Cornerstone BioPharma, Inc. and Aristos Pharmaceuticals, Inc. and the \$500,000 cash deposited by the Company's President and Chief Executive Officer.

**NOTE 4: NOTE PAYABLE****Carolina Note**

In April 2004, the Company executed a promissory note with Carolina Pharmaceuticals Ltd. ( Carolina Pharmaceuticals ), an entity under common control with the Company, to borrow up to \$15.0 million for five years with an annual interest rate of 10% ( Carolina Note ). The Company borrowed \$13.0 million under the Carolina Note in April 2004. In June 2006, the Company and Carolina Pharmaceuticals agreed to offset approximately \$3.6 million in principal and \$1.8 million in accrued interest outstanding under the Carolina Note against equal amounts due to the Company from a related party.

As of March 31, 2008 and December 31, 2007, approximately \$9.4 million in principal was outstanding under this agreement plus approximately \$1.7 million and \$1.5 million in accrued interest, respectively. The

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

outstanding principal and accrued interest are due in 2009. As of March 31, 2008, the fair value of the Carolina Note was approximately \$8.4 million.

**NOTE 5: STOCKHOLDERS DEFICIT**

As of March 31, 2008 and December 31, 2007 Cornerstone BioPharma Holdings, Inc. was authorized to issue 50,000,000 shares of common stock par value \$0.0001. As of March 31, 2008, the Company had outstanding 24,926,150 shares of \$0.0001 par value common stock.

**Restricted Common Stock**

The Company required certain employees to enter into restricted common stock agreements that would allow them to vest in their stock over time. The Company has the right to purchase the unvested portion of the restricted common stock on termination of employment for the original purchase price per share, which in management's opinion approximated fair value on the date of issuance. The stock vests 25% annually. No restricted stock vested during the first three months of 2008.

**NOTE 6: STOCK OPTIONS**

All stock-based awards are accounted for at their fair market value in accordance with SFAS No. 123 (revised 2004), *Share Based Payment* ( SFAS 123(R) ) and EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.

The following table summarizes the stock option activity for the period of January 1, 2008 through March 31, 2008:

	<b>Available Option Shares</b>	<b>Granted Options Outstanding</b>	<b>Weighted- Average Exercise Price</b>
Balance as of January 1, 2008	2,896,512	7,604,838	\$ 0.31
Cancelled	10,000	(10,000)	0.10
Balance as of March 31, 2008	2,906,512	7,594,838	\$ 0.31

There were no options granted or exercised in the three months ended March 31, 2008.

As of March 31, 2008, the aggregate intrinsic value of options outstanding was \$1,783,819 and the aggregate intrinsic value of options exercisable was \$1,068,758.

The following table summarizes the stock options vested and expected to vest as of March 31, 2008:



	<b>Number of Options</b>	<b>Weighted-Average Remaining Contractual Life (In Years)</b>	<b>Weighted-Average Exercise Price</b>
Outstanding	7,594,838	8.54	\$ 0.31
Exercisable	3,290,171	8.18	\$ 0.11

F-96

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

The following table summarizes information about the Company's stock options as of March 31, 2008:

<b>Exercise Price</b>	<b>Options Outstanding</b>	<b>Weighted-Average Contractual Life (Years)</b>	<b>Options Exercisable</b>
\$0.10	2,657,338	7.81	2,033,671
0.25	165,000	7.25	136,250
0.42	4,536,500	8.96	1,120,250
\$0.48	226,000	9.55	
	7,594,838		3,290,171

As of March 31, 2008, there was approximately \$538,000 of total unrecognized compensation cost related to nonvested stock-based compensation arrangements, which is expected to be recognized over a weighted-average period of 2.84 years.

During the three months ended March 31, 2008, the Company recorded approximately \$83,000 in employee stock-based compensation expense and \$1,000 in non-employee stock-based compensation expense. During the three months ended March 31, 2007, the Company recorded approximately \$48,000 in employee stock-based compensation expense and approximately \$1,000 in non-employee stock-based compensation expense.

Determining the appropriate fair value model and the related assumptions requires judgment. The fair value of each option grant is estimated using the Black-Scholes-Merton option-pricing model on the date of grant as follows:

	<b>Three Months Ended March 31, 2007</b>
Estimated dividend yield	0.00%
Expected stock price volatility	68.00%
Risk-free interest rate	4.48
Expected life of option (in years)	6.04
Weighted-average fair value per share	\$ 0.42

The expected volatility rates are estimated based on the actual volatility of comparable public companies over the expected life. The expected life represents the average time that options that vest are expected to be outstanding. The expected life of employee stock options is based on the mid-point between the vesting date and the contractual term in accordance with the simplified method prescribed in SAB No. 107, *Share-Based Payment*, and the expected life for stock-based compensation granted to non-employees is the contractual life. The risk-free rate is based on the U.S. Treasury yield curve during the expected life of the option.

**NOTE 7: LEASES**

**Operating Leases**

The Company leases its facilities and certain equipment and automobiles under noncancelable operating leases expiring at various dates through 2010. Rent expense was approximately \$127,000 and \$111,000 during the three months ended March 31, 2008 and 2007, respectively.

F-97

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

Future minimum payments under non-cancelable operating leases with initial terms of one year or more consist of the following as of March 31, 2008 (in thousands):

2008	\$ 181
2009	60
2010	11
Total minimum lease payments	\$ 252

**NOTE 8: INCOME TAXES**

Deferred income tax assets and liabilities are computed annually for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

The Company's consolidated financial statements include the accounts of Cornerstone BioPharma Holdings, Inc., Cornerstone BioPharma, Inc., Cornerstone Biopharma, Ltd., and Aristos Pharmaceuticals, Inc. Cornerstone Biopharma, Ltd. is an Anguilla international business company and was taxed as a foreign corporation for U.S. tax purposes in 2007 and 2006. Because Cornerstone Biopharma, Ltd. is not subject to income tax in Anguilla, the Company's consolidated financial statements do not include a provision for income taxes for this entity. Cornerstone Biopharma, Ltd.'s income would have been taxed to the owner of Cornerstone BioPharma Holdings, Inc. if Cornerstone Biopharma, Ltd. had issued dividends to Cornerstone BioPharma Holdings, Inc. or if Cornerstone BioPharma Holdings, Inc. had sold the stock of this subsidiary.

The provision for income taxes includes the following (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
Current:		
Federal	\$ 260	\$ 504
State	59	128
Total	319	632
Deferred:		

Federal  
State

Total

Total tax provision	\$ 319	\$ 632
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Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

F-98

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

Significant components of the Company's deferred tax assets as of March 31, 2008 and December 31, 2007 are as follows (in thousands):

	<b>March 31, 2008</b>	<b>December 31, 2007</b>
Current:		
Deferred tax assets:		
Accounts receivable, net	\$ 37	\$ 31
Inventories, net	253	177
Accrued expenses	3,005	2,881
Valuation allowance	(3,295)	(3,089)
Total current deferred tax assets	\$	\$
	<b>March 31, 2008</b>	<b>December 31, 2007</b>
Noncurrent:		
Deferred tax assets:		
Tax loss carryforwards	\$ 489	\$ 656
Deferred compensation	203	203
Product license rights, net	118	244
Organizational costs, net		2
Tax credits	62	62
Valuation allowance	(846)	(1,143)
Total noncurrent deferred tax assets	26	24
Deferred tax liabilities:		
Property and equipment, net	26	24
Net deferred tax asset – noncurrent		
Total net deferred tax asset	\$	\$

Income taxes computed at the statutory federal income tax rate of 34% are reconciled to the provision for income taxes as follows (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
United States federal tax at statutory rate	\$ 336	\$ 853
State taxes (net of federal benefit)	42	106
Nondeductible expenses	66	44
Other	(34)	34
Increase in valuation allowance	(91)	(405)
Provision for income taxes	\$ 319	\$ 632

F-99

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets. The valuation allowance decreased by approximately \$91,000 for the period ended March 31, 2008.

As of March 31, 2008, the Company has federal and state tax net operating loss carryforwards of approximately \$1,283,300 and \$1,114,800 that expire beginning in the year 2022 and 2020, respectively.

The Tax Reform Act of 1986 contains provisions that limit the Company's ability to utilize the net operating loss carryforwards in the case of certain events, including significant changes in ownership interests. If the Company's net operating loss carryforwards are limited and the Company has taxable income that exceeds the permissible yearly net operating loss carryforwards, the Company would incur a federal income tax liability even though net operating loss carryforwards would be available in future years.

**NOTE 9: RELATED PARTY TRANSACTIONS**

**Stockholders**

During the three months ended March 31, 2008 and 2007, the Company made advances to its President and Chief Executive Officer, who is also the Company's majority stockholder, of approximately \$4,000 and \$204,000, respectively. As of March 31, 2008 and December 31, 2007, unpaid advances were approximately \$652,000 and \$648,000, respectively, and are included in amounts due from related parties as of those dates.

The Company has certain agreements with its President and Chief Executive Officer that provide certain benefits related to a qualified termination or change of control, as defined by the agreements.

**Other Related Parties**

As of March 31, 2008, the Company owes Carolina Pharmaceuticals approximately \$260,000 in accrued royalties related to the sale of Humibid® and DECONSAL®. This amount is included in accrued royalties as disclosed in Note 2. The Company paid \$750,000 to Carolina Pharmaceuticals for royalties in 2006. The Company did not pay any royalties to Carolina Pharmaceuticals in 2005 or 2007. The Company's President and Chief Executive Officer is a controlling stockholder of Carolina Pharmaceuticals.

In May 2005, the Company licensed certain product rights to Auriga Laboratories, Inc. (Auriga), which is also owned in part and/or directed by some of the Company's stockholders. The effective date of the agreement is August 1, 2005. The Company received a royalty ranging from 8% to 30% of net sales, depending on the level of net sales. The Company's royalty is not to exceed \$1.7 million on an annual basis. Auriga assumed responsibility for royalty payments to the previous owner of the product rights as of the effective date. In 2006, the royalty agreement with Auriga was amended to reduce the royalty rates from 30% to 5% of net sales in a specific calendar quarter. The amendment also provided for Auriga to issue the Company 200,000 shares of its common stock. The fair value of the stock, determined as the trading price on date of grant discounted 15% for lack of marketability due to a one-year lock up period, was approximately \$332,000. The Company included this amount in royalty agreement revenues.



The Company recognized royalty agreement revenues under the agreements with Auriga of approximately \$58,000 and \$114,000 for the three months ended March 31, 2008 and 2007, respectively.

F-100

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE 10: CONTRACTUAL AGREEMENTS AND OBLIGATIONS**

**Royalties**

The Company has contractual obligations to pay royalties to the former owners of certain product rights that have been acquired by or licensed to the Company. These royalties are based on a percentage of net sales of the particular licensed product.

In August 2006, the Company entered into an agreement with Pharmaceutical Innovations, LLC ( Pharmaceutical Innovations ) for an exclusive license to a U.S. patent and know-how to manufacture, package, market and distribute various day-night products. In exchange for these rights, the Company was required to pay Pharmaceutical Innovations a special royalty of 8.5% of initial net sales of day-night products up to a total of \$250,000. The Company paid this special royalty in 2006 and 2007. In addition, the Company is obligated to pay royalties based on a percentage of the products' annual net sales. The royalty rate increases as the annual net sales increase. Minimum annual royalties are \$300,000 per year under this agreement during the life of the licensed patent based on the products currently marketed by the Company.

**Inventory Purchases**

The Company purchases inventory from pharmaceutical manufacturers. During the three months ended March 31, 2008 and 2007, two vendors accounted for 23% and 36% of Company purchases, respectively.

The Company has entered into an agreement with Vintage to exclusively manufacture two prescription pain products acquired from Vintage for prices established by the agreement, subject to renegotiation at each anniversary date. The agreement expires in July 2009 and may be renewed for subsequent one-year terms.

In connection with the Company's license agreement with Meiji, the Company also entered into a supply agreement with Meiji to purchase minimum quantities of cefditoren pivoxil, the API in SPECTRACEF, exclusively from Meiji. Under this agreement, Cornerstone is required to purchase the minimum quantities of cefditoren pivoxil necessary to support targeted gross sales of SPECTRACEF after the SPECTRACEF product launch of \$8.0 million for year one, \$11.0 million for year two, \$13.0 million for year three, \$17.0 million for year four and \$24.0 million for year five. If the Company does not meet its minimum purchase requirement in a given year, the Company must pay Meiji an amount equal to 50% of the shortfall in that year. The Company expects to exceed the minimum purchase requirements.

In July 2007, the Company entered into a supply agreement with Bayer HealthCare, LLC ( Bayer ) to purchase minimum quantities of the bulk tablets for the ALLERX Dose Pack family of products from Bayer during calendar years 2008 and 2009. An additional one-time cost of up to \$135,000 will be due on December 31, 2009 if the Company fails to meet the minimum annual purchase requirement of 27.0 million tablets per year for 2008 and 2009. The Company expects to exceed the minimum purchase requirements.

As of March 31, 2008, the Company had outstanding purchase commitments related to inventory totaling approximately \$3.4 million.

**Co-promotion Agreements**

In February 2006, the Company signed a co-promotion agreement with Ascend Therapeutics, Inc. ( Ascend ) to provide detailing of a product to a specific physician population. As compensation, the Company paid a fee for detailing the product equal to 50% of net sales. This agreement was terminated in March 2008.

In March 2007 and June 2007, the Company entered into co-promotion agreements with SJ Pharmaceuticals, LLC ( SJ Pharmaceuticals ) to co-promote two of the Company's product lines. Under these agreements, the Company pays SJ Pharmaceuticals fees based on a percentage of the net profits of the products sold above a

F-101

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

specified baseline based upon prescriptions by assigned, targeted prescribers within assigned sales territories. These targeted prescribers are mutually agreed upon by the Company and SJ Pharmaceuticals prior to the start of each quarter.

In April 2007, the Company entered into a co-promotion agreement with Atley Pharmaceuticals, Inc. ( Atley Pharmaceuticals ) to co-promote a prescription pain product beginning July 1, 2007. Under the agreement, the Company pays Atley Pharmaceuticals fees based on a percentage of the net profits from sales of the product above a specified baseline within assigned sales territories.

Each of these co-promotion agreements is subject to sunset fees that require the Company to pay additional fees for up to one year in the event of certain defined terminations of the agreements.

**Sales and Marketing Agreement**

In September 2005, the Company entered into a sales and marketing agreement with Pliva, Inc. ( Pliva ). Under this agreement, the Company receives all revenues, less usual and customary discounts and a distribution fee to Pliva calculated as a percentage of net revenues that Pliva generates on sales of Propoxyphene-APAP 100-500. The current term of the agreement expires December 31, 2008. The Company has given Pliva notice that at the end of the current term the Company will terminate the agreement.

**Settlements**

***Adams Respiratory Therapeutics, Inc.***

In October 2004, the Company was included as a defendant in litigation with a related party, Carolina Pharmaceuticals, Inc., by Adams Respiratory Therapeutics, Inc. ( Adams ) that alleged trademark infringement, false advertising and unfair competition claims and sought damages and injunctive relief. The Company vigorously defended these allegations and filed various counterclaims. In January 2005, Adams and the Company entered into an agreement under which in February 2005 the Company received all of the rights to the ALLERX products held by Adams and Adams received all of the rights to the Humibid family of products held by the Company. Additionally, the parties released each other from all claims and damages in the above mentioned lawsuit. The agreement required the Company to assume the financial responsibility for the first \$1.0 million of returned Humibid product that was sold by the Company prior to February 15, 2005 and returned to Adams during the 18-month period beginning February 15, 2005. The Company recorded \$1.0 million in accrued expenses in the consolidated balance sheet as of March 31, 2008 for this Humibid liability.

The Company also had \$746,000 in accrued royalty expenses related to ALLERX sales as of March 31, 2008. Conversely, Adams was financially responsible for the first \$1.0 million of ALLERX product returns for the same 18-month period. The Company recorded approximately \$355,000 in accounts receivable in the consolidated balance sheets as of March 31, 2008. After the 18-month period or the \$1.0 million threshold is met, the agreement provided that the Company would have the responsibility for all ALLERX product returns whether sold by the Company or Adams and Adams would bear the same liability for Humibid products. In connection with this agreement, Adams is obligated to pay the Company a royalty ranging from 1% to 2% of net Humibid sales for a period of three years after

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February 15, 2005 with a minimum annual royalty of \$50,000. The Company has recorded \$108,000 in accounts receivable in the consolidated balance sheets as of March 31, 2008 related to the minimum royalty.

In 2006, a major wholesaler indicated that it was in possession of a significant amount of Humibid prescription inventory. Adams filed a complaint alleging that the Company and Carolina Pharmaceuticals, Inc. did not disclose the outstanding inventory in accordance with the prior agreement and are therefore financially responsible for the returns. The Company and Carolina Pharmaceuticals, Inc. believed they were not liable for

F-102

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

these returns under the agreement and filed a counterclaim. Since all Humibid prescription products were sold by Carolina Pharmaceuticals, Inc., the Company did not accrue any amounts related to this claim.

In May 2008, the Company settled the dispute with Adams. The agreement provides that all parties to the settlement are to be released from all legal claims made prior to January 2008 and that the Company and Carolina Pharmaceuticals, Inc. shall pay to Reckitt Benckiser, Inc., the parent of Adams, \$1.5 million in three installments to be paid as follows: \$500,000 by June 20, 2008; \$500,000 by June 30, 2008; and \$500,000 by September 30, 2008. In exchange, the Company is released from all liabilities. The total net amount accrued on the Company's consolidated balance sheet as of March 31, 2008 was approximately \$1.3 million. As of June 30, 2008, the Company has paid \$1.0 million related to the settlement agreement. The Company expects to pay \$291,000 on September 30, 2008. Carolina Pharmaceuticals, Inc. will make the remaining payment of \$209,000.

***Others***

In November 2006, the Company filed a legal complaint against a pharmaceutical company, certain affiliates of the pharmaceutical company and the manufacturer of a product launched by the pharmaceutical company that the Company believed infringed upon the patent of one of its products. By January 2007, the disputes with all involved parties were settled. The terms of the settlements required the parties to admit and acknowledge that the claims of the patent are valid and enforceable and covenant that the parties will not infringe on the claims of the patent by making, using, selling or offering for sale any product that would infringe on the patent. The settlements provided that the Company pay the parties for the value of certain inventory on hand, which was destroyed. The Company accrued approximately \$256,000 in 2006 related to these potential inventory purchases. The total actual inventory payments made related to the settlement in 2007 amounted to approximately \$236,000, and the excess accrual of \$20,000 was reversed as of December 31, 2007.

In addition, as part of the settlement, the Company also committed to pay \$75,000 for trademark rights. The Company also made this payment in 2007.

In response to a claim of infringement filed by the Company in early 2008, a pharmaceutical company has filed a counterclaim that the patent, which is licensed to the Company, is invalid and moved to stay the litigation pending the re-examination of the Company's patent. No monetary relief has been requested in the counterclaim. The court granted defendants' motion and stayed the litigation pending the re-examination of the Company's patent in February 2008. Separately, the U.S. Patent and Trademark Office ordered a re-examination of the patent. Additionally, in June 2008, the pharmaceutical company requested that the U.S. Patent and Trademark Office re-examine a related second patent licensed to the Company by an affiliate of the licensor of the first patent, which is not at issue in the litigation. In concert with the licensor of the patents, the Company intends to vigorously pursue its claims and defend the counterclaim. The Company's intellectual property counsel has concluded that valid arguments exist for distinguishing the claims of the Company's patents over the references cited in the requests for re-examination. If the United States Patent and Trademark Office invalidates some or all of the claims under these patents, the Company could be exposed to increased generic competition relating to its various day-night products, and its future operating and financial results could be adversely affected. Because no monetary relief has been requested in the counterclaim, no amount has been accrued in these consolidated financial statements.

**Product Agreements**

In August 2006, the Company loaned Neos \$500,000 under a secured subordinated promissory note agreement. In December 2006, the Company entered into a product development agreement with Neos providing the Company with an exclusive license to certain products under development utilizing Neos' s time

F-103

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**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

release suspension technology. Under the terms of the agreement, the note with Neos was forgiven. The Company has recorded the \$500,000 consideration as product rights related to the time release suspension technology. The agreement requires Neos to develop each product at its own expense up to a defined milestone. After that milestone is achieved, the Company is required to reimburse Neos 110% of all direct costs incurred and pay \$150 per hour for personnel time incurred in the development of the products. The Company will also make milestone payments up to \$1.0 million for each product based on specific events. No development costs or milestone payments have been made or accrued as of March 31, 2008. Upon commercialization, the Company would also pay Neos royalties based on a percentage of net sales.

During 2007, the Company entered various research and development agreements. As of March 31, 2008, the Company had outstanding commitments related to ongoing research and development contracts totaling approximately \$811,000.

**Severance**

Selected executive employees of the Company have employment agreements which provide for severance payments ranging from three to 12 months of salary and benefits upon termination, depending on the reasons for the termination. The executive would also be required to execute a release and settlement agreement. No amount has been accrued for severance as of March 31, 2008.

**NOTE 11: SUBSEQUENT EVENTS**

**Lease Agreement**

In May 2008, the Company entered into a lease agreement for a new corporate headquarters, which will occupy approximately 14,900 square feet of office space and is located in the Crescent Lakeside office complex, in Cary, North Carolina. The lease has an initial term that commences in December 2008 and expires in March 2016. Initial annual base rent under the lease is approximately \$350,000 with annual rent increases of approximately 3%. The Company also has an option to renew the lease for an additional five-year term through March 2021.

**Proposed Merger with Critical Therapeutics, Inc.**

On May 1, 2008, the Company and Critical Therapeutics, Inc. ( Critical Therapeutics ) entered into a merger agreement pursuant to which Neptune Acquisition Corp., a wholly owned subsidiary of Critical Therapeutics, will merge with and into the Company (the Merger ), with the Company continuing after the merger as the surviving company and a wholly owned subsidiary of Critical Therapeutics (the Merger Agreement ). If the Merger is completed, at the effective time of the Merger, all outstanding shares of the Company 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 the Company s common stock will be assumed by Critical Therapeutics and become options and warrants to purchase Critical Therapeutics common stock. The Merger Agreement provides that, at the effective time of the Merger, Critical Therapeutics will issue to the Company s stockholders, and assume the Company s 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 contemplated reverse stock split of Critical



Therapeutics common stock to occur in connection with the Merger. Immediately following the effective time of the Merger, the Company's stockholders will own approximately 70%, and Critical Therapeutics stockholders will own approximately 30%, of Critical Therapeutics common stock, after giving effect to shares issuable pursuant to the Company's outstanding options and warrants, but without giving effect to any shares issuable pursuant to Critical Therapeutics outstanding options and warrants. The exchange ratio per share of the Company's common stock will be based on the number of shares of the Company's common stock

**CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

outstanding on a fully diluted basis immediately prior to the effective time of the Merger and will not be determined until that time.

The consummation of the Merger is subject to a number of closing conditions, including the approval of both the Company's stockholders and Critical Therapeutics' stockholders, approval by The NASDAQ Stock Market LLC of Critical Therapeutics' application for re-listing of its common stock in connection with the Merger, the continued availability of its products and other customary closing conditions. As a condition to the Merger, Carolina Pharmaceuticals 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 shares of the Company's common stock prior to the effective time of the merger. The Company is targeting a closing of the transaction in the fourth quarter of 2008.

Immediately prior to the effective time of the Merger, Critical Therapeutics has agreed to effect a reverse stock split of its common stock whereby each issued and outstanding share of its common stock will be reclassified and combined into a fractional number of shares of common stock. The reverse stock split ratio is to be mutually agreed upon by the Company and 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 the initial listing standards for The NASDAQ Capital Market.

The Merger Agreement provides for the payment of a termination fee of \$1.0 million by each of the Company and Critical Therapeutics 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 the Company for up to \$150,000 in expenses and the Company has agreed to reimburse Critical Therapeutics for up to \$100,000 in expenses.

**AGREEMENT AND PLAN OF MERGER**

by and among  
CRITICAL THERAPEUTICS, INC.,  
NEPTUNE ACQUISITION CORP.  
and  
CORNERSTONE BIOPHARMA HOLDINGS, INC.  
Dated as of May 1, 2008

A-1

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## TABLE OF CONTENTS

	Page
<b>ARTICLE I THE MERGER</b>	A-9
1.1 <u>Effective Time of the Merger</u>	A-9
1.2 <u>Closing</u>	A-9
1.3 <u>Effects of the Merger</u>	A-9
1.4 <u>Certificate of Incorporation; Bylaws</u>	A-9
1.5 <u>Directors and Officers of the Surviving Corporation</u>	A-9
 <b>ARTICLE II CONVERSION OF SECURITIES</b>	 A-10
2.1 <u>Reverse Split of Public Company Common Stock</u>	A-10
2.2 <u>Conversion of Capital Stock</u>	A-10
2.3 <u>Exchange of Certificates</u>	A-11
2.4 <u>Merger Partner Stock Plans and Merger Partner Warrants</u>	A-13
2.5 <u>Dissenting Shares</u>	A-14
 <b>ARTICLE III REPRESENTATIONS AND WARRANTIES OF MERGER PARTNER</b>	 A-14
3.1 <u>Organization, Standing and Power</u>	A-15
3.2 <u>Capitalization</u>	A-15
3.3 <u>Subsidiaries</u>	A-17
3.4 <u>Authority; No Conflict; Required Filings and Consents</u>	A-18
3.5 <u>Merger Partner Financial Statements; Information Provided</u>	A-19
3.6 <u>No Undisclosed Liabilities</u>	A-20
3.7 <u>Absence of Certain Changes or Events</u>	A-20
3.8 <u>Taxes</u>	A-20
3.9 <u>Owned and Leased Real Properties</u>	A-22
3.10 <u>Intellectual Property</u>	A-22
3.11 <u>Contracts</u>	A-24
3.12 <u>Litigation</u>	A-25
3.13 <u>Environmental Matters</u>	A-25
3.14 <u>Employee Benefit Plans</u>	A-26
3.15 <u>Compliance With Laws</u>	A-28
3.16 <u>Permits and Regulatory Matters</u>	A-28
3.17 <u>Employees</u>	A-29
3.18 <u>Insurance</u>	A-30
3.19 <u>No Existing Discussions</u>	A-30
3.20 <u>Brokers; Fees and Expenses</u>	A-30
3.21 <u>Controls and Procedures, Certifications and Other Matters Relating to the Sarbanes Act</u>	A-30
3.22 <u>Certain Business Relationships With Affiliates</u>	A-31
3.23 <u>Books and Records</u>	A-31
 <b>ARTICLE IV REPRESENTATIONS AND WARRANTIES OF PUBLIC COMPANY AND THE TRANSITORY SUBSIDIARY</b>	 A-31
4.1 <u>Organization, Standing and Power</u>	A-31
4.2 <u>Capitalization</u>	A-32

4.3	<u>Subsidiaries</u>	A-33
4.4	<u>Authority; No Conflict; Required Filings and Consents</u>	A-34
4.5	<u>SEC Filings; Financial Statements; Information Provided</u>	A-35
4.6	<u>No Undisclosed Liabilities</u>	A-37
4.7	<u>Absence of Certain Changes or Events</u>	A-37
4.8	<u>Taxes</u>	A-37

4.9	<u>Owned and Leased Real Properties</u>	A-38
4.10	<u>Intellectual Property</u>	A-39
4.11	<u>Agreements, Contracts and Commitments</u>	A-39
4.12	<u>Litigation</u>	A-40
4.13	<u>Environmental Matters</u>	A-41
4.14	<u>Employee Benefit Plans</u>	A-41
4.15	<u>Compliance With Laws</u>	A-43
4.16	<u>Permits and Regulatory Matters</u>	A-43
4.17	<u>Employees</u>	A-44
4.18	<u>Insurance</u>	A-44
4.19	<u>No Existing Discussions</u>	A-45
4.20	<u>Opinion of Financial Advisor</u>	A-45
4.21	<u>Section 203 of the DGCL Not Applicable</u>	A-45
4.22	<u>Brokers: Fees and Expenses</u>	A-45
4.23	<u>Operations of the Transitory Subsidiary</u>	A-45
4.24	<u>Controls and Procedures, Certifications and Other Matters Relating to the Sarbanes Act</u>	A-45
<b>ARTICLE V CONDUCT OF BUSINESS</b>		A-46
5.1	<u>Covenants of Merger Partner</u>	A-46
5.2	<u>Covenants of Public Company</u>	A-48
5.3	<u>Confidentiality</u>	A-51
<b>ARTICLE VI ADDITIONAL AGREEMENTS</b>		A-51
6.1	<u>No Solicitation</u>	A-51
6.2	<u>Proxy Statement/Prospectus; Registration Statement</u>	A-53
6.3	<u>NASDAQ Listing</u>	A-54
6.4	<u>Access to Information</u>	A-54
6.5	<u>Stockholder Approval</u>	A-54
6.6	<u>Legal Conditions to Merger</u>	A-55
6.7	<u>Public Disclosure</u>	A-56
6.8	<u>Section 368(a) Reorganization</u>	A-56
6.9	<u>D&amp;O Insurance: Indemnification</u>	A-57
6.10	<u>Notification of Certain Matters</u>	A-57
6.11	<u>Headquarters of Public Company</u>	A-58
6.12	<u>Corporate Identity</u>	A-58
6.13	<u>Succession</u>	A-58
6.14	<u>Board of Directors of Public Company</u>	A-58
6.15	<u>Employee Communications</u>	A-58
6.16	<u>FIRPTA Tax Certificates</u>	A-58
<b>ARTICLE VII CONDITIONS TO MERGER</b>		A-58
7.1	<u>Conditions to Each Party's Obligation To Effect the Merger</u>	A-58
7.2	<u>Additional Conditions to the Obligations of Public Company and the Transitory Subsidiary</u>	A-59
7.3	<u>Additional Conditions to the Obligations of Merger Partner</u>	A-60
<b>ARTICLE VIII TERMINATION AND AMENDMENT</b>		A-62

8.1	<u>Termination</u>	A-62
8.2	<u>Effect of Termination</u>	A-63
8.3	<u>Fees and Expenses</u>	A-64
8.4	<u>Amendment</u>	A-65
8.5	<u>Extension; Waiver</u>	A-65

<b>ARTICLE IX</b>	<b>MISCELLANEOUS</b>	A-65
9.1	<u>Nonsurvival of Representations, Warranties and Agreements</u>	A-65
9.2	<u>Notices</u>	A-65
9.3	<u>Entire Agreement</u>	A-66
9.4	<u>No Third Party Beneficiaries</u>	A-66
9.5	<u>Assignment</u>	A-66
9.6	<u>Severability</u>	A-66
9.7	<u>Counterparts and Signature</u>	A-67
9.8	<u>Interpretation</u>	A-67
9.9	<u>Governing Law</u>	A-67
9.10	<u>Remedies</u>	A-67
9.11	<u>Submission to Jurisdiction</u>	A-67
9.12	<u>WAIVER OF JURY TRIAL</u>	A-68
9.13	<u>Operating Company Guarantee</u>	A-68
Schedule A-1	Merger Partner Key Stockholders	A-70
Schedule A-2	Public Company Key Stockholders	A-71
Schedule 6.13	Officer Appointments	A-72
Schedule 6.14(a)	Director Appointments	A-73
Schedule 6.14(b)	Director Resignations	A-74
Exhibit A-1	Form of Merger Partner Stockholder Agreement	A-75
Exhibit A-2	Form of Merger Partner Noteholder Agreement	A-84
Exhibit A-3	Form of Public Company Stockholder Agreement	A-94
Exhibit B	Form of Certificate of Incorporation of the Surviving Corporation	A-102



**TABLE OF DEFINED TERMS**

Terms	Cross Reference in Agreement
Acquisition Proposal	Section 6.1(f)
Adjusted Warrant	Section 2.4(e)
Affiliate	Section 3.2(e)
Agreement	Preamble
Antitrust Laws	Section 6.6(b)
Bankruptcy and Equity Exception	Section 3.4(a)
Carolina Note	Preamble
Carolina Pharmaceuticals Bermuda	Preamble
Certificate of Merger	Section 1.1
Certificates	Section 2.3(a)
Closing	Section 1.2
Closing Date	Section 1.2
Code	Preamble
Comparable Product	Section 3.16(e)
Confidentiality Agreement	Section 5.3
DGCL	Preamble
Dissenting Shares	Section 2.2(c)
Effective Time	Section 1.1
Employee Benefit Plan	Section 3.14(l)(i)
Environmental Law	Section 3.13(b)
ERISA	Section 3.14(l)(ii)
ERISA Affiliate	Section 3.14(l)(iii)
Exchange Act	Section 3.4(c)
Exchange Agent	Section 2.3(a)
Exchange Fund	Section 2.3(a)
Exchange Ratio	Section 2.2(c)
FDA	Section 3.16(a)
GAAP	Section 3.5(a)
Governmental Entity	Section 3.4(c)
Hazardous Substance	Section 3.13(c)
HSR Act	Section 6.6(a)
Indemnified Parties	Section 6.9(b)
Intellectual Property	Section 3.10(e)(i)
IRS	Section 3.8(b)
Lazard	Section 4.20
Lien	Section 3.4(b)
Merger	Preamble
Merger Partner	Preamble
Merger Partner Authorizations	Section 3.16(a)
Merger Partner Balance Sheet	Section 3.5(a)
Merger Partner Balance Sheet Date	Section 3.5(a)
Merger Partner Board	Preamble

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Merger Partner Common Stock	Preamble
Merger Partner Counsel	Section 7.3(d)
Merger Partner Disclosure Schedule	Article III
Merger Partner Employee Plans	Section 3.14(a)
Merger Partner Financial Statements	Section 3.5(a)
Merger Partner Insurance Policies	Section 3.18

A-5

---

Terms	Cross Reference in Agreement
Merger Partner Intellectual Property	Section 3.10(b)
Merger Partner Leases	Section 3.9(b)
Merger Partner Material Adverse Effect	Section 3.1
Merger Partner Noteholder Agreement	Preamble
Merger Partner Stock Options	Section 2.4(a)
Merger Partner Stock Plans	Section 2.4(a)
Merger Partner Stockholder Agreements	Preamble
Merger Partner Stockholder Approval	Section 3.4(a)
Merger Partner Third Party Intellectual Property	Section 3.10(b)
Merger Partner Voting Proposal	Section 3.4(a)
Merger Partner Warrants	Section 3.2(d)
NASDAQ	Section 2.1(b)
New Merger Partner Audit Firm	Section 3.5(b)
Operating Company	Preamble
Ordinary Course of Business	Section 3.3(d)
Outside Date	Section 8.1(b)
Patent Rights	Section 3.10(e)(ii)
Proxy Statement/Prospectus	Section 3.5(c)
Public Company	Preamble
Public Company Authorizations	Section 4.16(a)
Public Company Balance Sheet	Section 4.5(b)
Public Company Board	Preamble
Public Company Charter Amendment	Section 2.1(a)
Public Company Common Stock	Section 2.1(a)(i)
Public Company Disclosure Schedule	Article IV
Public Company Employee Plans	Section 4.14(a)
Public Company Form 10-K	Section 4.5(b)
Public Company Insurance Policies	Section 4.18
Public Company Intellectual Property	Section 4.10(b)
Public Company Leases	Section 4.9(b)
Public Company Material Adverse Effect	Section 4.1
Public Company Material Contracts	Section 4.11(a)
Public Company Meeting	Section 3.5(c)
Public Company Preferred Stock	Section 4.2(a)
Public Company Recent SEC Documents	Section 4.6
Public Company SEC Documents	Section 4.5(a)
Public Company Stock Options	Section 4.2(c)
Public Company Stock Plans	Section 4.2(c)
Public Company Stockholder Agreements	Preamble
Public Company Stockholder Approval	Section 3.5(c)
Public Company Third Party Intellectual Property	Section 4.10(b)
Public Company Voting Proposals	Section 3.5(c)
Public Company Warrants	Section 4.2(c)
Registration Statement	Section 3.5(d)
Regulation M-A Filing	Section 3.5(c)

Representatives	Section 6.1(a)
Reverse Stock Split	Section 2.1(a)(i)
Sarbanes Act	Section 4.5(a)
SEC	Section 3.4(c)
Securities Act	Section 3.2(e)

A-6

---

Terms	Cross Reference in Agreement
Specified Time	Section 6.1(a)(ii)
Subsidiary	Section 3.3(a)
Superior Proposal	Section 6.1(f)
Surviving Corporation	Section 1.3
Tax Returns	Section 3.8(a)
Taxes	Section 3.8(a)
Trademarks	Section 3.10(e)(iii)
Transitory Subsidiary	Preamble
WilmerHale	Section 7.2(d)
Written Consents	Section 3.4(d)

## AGREEMENT AND PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER (this Agreement ), dated as of May 1, 2008, is by and among Critical Therapeutics, Inc., a Delaware corporation ( Public Company ), Neptune Acquisition Corp., a Delaware corporation and a wholly owned subsidiary of Public Company (the Transitory Subsidiary ), and Cornerstone BioPharma Holdings, Inc., a Delaware corporation ( Merger Partner ).

WHEREAS, the Board of Directors of Public Company (the Public Company Board ) and the Board of Directors of Merger Partner (the Merger Partner Board ) each deem it advisable and in the best interests of their respective corporation and its stockholders that Public Company and Merger Partner combine in order to advance the long-term business interests of Public Company and Merger Partner;

WHEREAS, the combination of Public Company and Merger Partner shall be effected through a merger (the Merger ) of the Transitory Subsidiary into Merger Partner in accordance with the terms of this Agreement and the General Corporation Law of the State of Delaware (the DGCL ), as a result of which Merger Partner will become a wholly owned subsidiary of Public Company;

WHEREAS, concurrently with the execution and delivery of this Agreement and as a condition and inducement to Public Company's willingness to enter into this Agreement, the stockholders of Merger Partner listed on Schedule A-1 to this Agreement have entered into Stockholder Agreements, dated as of the date of this Agreement, in the form attached hereto as Exhibit A-1 (the Merger Partner Stockholder Agreements ), pursuant to which such stockholders have, among other things, agreed (i) to give Public Company a proxy to vote all of the shares of capital stock of Merger Partner that such stockholders own and (ii) not to transfer or otherwise dispose of any shares of capital stock of Merger Partner that such stockholders own or, for 180 days after the Effective Time, any Public Company Common Stock received in exchange therefor pursuant to the Merger;

WHEREAS, concurrently with the execution and delivery of this Agreement and as a condition and inducement to Public Company's willingness to enter into this Agreement, Carolina Pharmaceuticals Ltd., a Bermuda Exempted Company ( Carolina Pharmaceuticals Bermuda ), the holder of that certain Promissory Note, dated April 19, 2004, with Cornerstone BioPharma, Inc., a Nevada corporation and a wholly owned subsidiary of Merger Partner ( Operating Company ), as amended by that certain Promissory Note Amendment and Waiver Agreement, dated June 6, 2006 (as amended, the Carolina Note ), has entered into a Noteholder Agreement, dated as of the date of this Agreement, in the form attached hereto as Exhibit A-2 (the Merger Partner Noteholder Agreement ), pursuant to which Carolina Pharmaceuticals Bermuda, among other things, has agreed (i) to exchange or convert the Carolina Note into the common stock, \$0.0001 par value per share, of Merger Partner (the Merger Partner Common Stock ) prior to the Effective Time in accordance with the terms of the Merger Partner Noteholder Agreement, (ii) to give Public Company a proxy to vote all of the shares of capital stock of Merger Partner that Carolina Pharmaceuticals Bermuda owns and (iii) not to transfer or otherwise dispose of any shares of Merger Partner Common Stock that Carolina Pharmaceuticals Bermuda owns or, for 180 days after the Effective Time, any Public Company Common Stock received in exchange therefor pursuant to the Merger;

WHEREAS, concurrently with the execution and delivery of this Agreement and as a condition and inducement to Merger Partner's willingness to enter into this Agreement, the stockholders of Public Company listed on Schedule A-2 to this Agreement have entered into Stockholder Agreements, dated as of the date of this Agreement, in the form attached hereto as Exhibit A-3 (the Public Company Stockholder Agreements ), pursuant to which such stockholders have, among other things, agreed to give Merger Partner a proxy to vote all of the shares of capital stock of Public Company that such stockholders own;

WHEREAS, for United States federal income tax purposes, it is intended that the Merger shall qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the Code );

A-8

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NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth below, Public Company, the Transitory Subsidiary and Merger Partner agree as follows:

## ARTICLE I

### THE MERGER

1.1 Effective Time of the Merger. Subject to the provisions of this Agreement, prior to the Closing, Public Company shall prepare (in a form reasonably acceptable to Merger Partner), and on the Closing Date or as soon as practicable thereafter Public Company and Merger Partner shall cause to be filed with the Secretary of State of the State of Delaware, a certificate of merger (the Certificate of Merger ) in such form as is required by, and executed by the Surviving Corporation in accordance with, the relevant provisions of the DGCL and shall make all other filings or recordings required under the DGCL. The Merger shall become effective upon the filing of the Certificate of Merger with the Secretary of State of the State of Delaware or at such later time as is established by Public Company and Merger Partner and set forth in the Certificate of Merger (the Effective Time ). The Certificate of Merger shall provide that the name of the Surviving Corporation as of and after the Effective Time shall be Cornerstone BioPharma Holdings, Inc.

1.2 Closing. The closing of the Merger (the Closing ) will take place at 10:00 a.m., Eastern time, on a date to be specified by Public Company and Merger Partner (the Closing Date ), which shall be no later than the second business day after satisfaction or waiver of the conditions set forth in Article VII (other than delivery of items to be delivered at the Closing and other than satisfaction of those conditions that by their nature are to be satisfied at the Closing, it being understood that the occurrence of the Closing shall remain subject to the delivery of such items and the satisfaction or waiver of such conditions at the Closing), at the offices of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., 2500 Wachovia Capitol Center, Raleigh, NC 27601, unless another date, place or time is agreed to in writing by Public Company and Merger Partner. It is the intention of the parties that the Closing shall occur as soon as practicable after the Public Company Meeting.

1.3 Effects of the Merger. At the Effective Time, the separate existence of the Transitory Subsidiary shall cease and the Transitory Subsidiary shall be merged with and into Merger Partner (Merger Partner following the Merger is sometimes referred to herein as the Surviving Corporation ), and the Merger shall have the effects set forth in the DGCL.

1.4 Certificate of Incorporation: Bylaws.

(a) The Certificate of Incorporation of the Surviving Corporation shall be amended at the Effective Time in its entirety to read in the form attached hereto as Exhibit B.

(b) The Bylaws of the Surviving Corporation immediately following the Effective Time shall be the same as the Bylaws of the Transitory Subsidiary immediately prior to the Effective Time, except that the name of the corporation set forth therein shall be changed to Cornerstone BioPharma Holdings, Inc.

1.5 Directors and Officers of the Surviving Corporation.

(a) The directors of Merger Partner immediately prior to the Effective Time shall be the initial directors of the Surviving Corporation, each to hold office in accordance with the Certificate of Incorporation and Bylaws of the Surviving Corporation.



(b) The officers of Merger Partner immediately prior to the Effective Time shall be the initial officers of the Surviving Corporation, each to hold office in accordance with the Certificate of Incorporation and Bylaws of the Surviving Corporation.

A-9

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## ARTICLE II

### CONVERSION OF SECURITIES

#### 2.1 Reverse Split of Public Company Common Stock.

(a) Immediately prior to the Effective Time, and subject to receipt of the Public Company Stockholder Approval, Public Company shall cause to be filed a Certificate of Amendment to its Certificate of Incorporation (the Public Company Charter Amendment ), whereby, upon the effectiveness of filing of the Public Company Charter Amendment, without any further action on the part of Public Company, Merger Partner or any stockholder of Public Company:

(i) Each share of common stock, \$0.001 par value per share, of Public Company ( Public Company Common Stock ) issued and outstanding immediately prior to the effective time specified in the Public Company Charter Amendment shall be reclassified and combined into and become a fractional number of fully paid and nonassessable shares of Public Company Common Stock to be mutually agreed upon by Public Company and Merger Partner (the Reverse Stock Split ).

(ii) Any shares of Public Company Common Stock held as treasury stock or owned by Public Company immediately prior to the filing of the Public Company Charter Amendment shall each be reclassified and combined into and become an identical fractional number of shares of Public Company Common Stock as determined by the Board of Directors of Public Company in connection with Section 2.1(a)(i).

(b) No certificates or scrip representing fractional shares of Public Company Common Stock shall be issued in connection with the Reverse Stock Split. Each holder of shares of Public Company Common Stock who would otherwise have been entitled to receive a fraction of a share of Public Company Common Stock (after taking into account all fractional shares of Public Company Common Stock otherwise issuable to such holder) shall be entitled to receive, in lieu thereof, upon surrender of such holder's certificate(s) representing such fractional shares of Public Company Common Stock, cash (without interest) in an amount equal to such fractional part of a share of Public Company Common Stock multiplied by the average last reported sales prices of Public Company Common Stock at the 4:00 p.m., Eastern time, end of regular trading hours on The NASDAQ Stock Market LLC ( NASDAQ ) during the ten consecutive trading days ending on the last trading day prior to the Effective Time.

(c) To give effect to, and as of the effective time of, the Reverse Stock Split, Public Company shall adjust and proportionately decrease the number of shares of Public Company Common Stock reserved for issuance upon exercise of, and adjust and proportionately increase the exercise price of, all options, warrants and other rights to acquire Public Company Common Stock.

(d) The Exchange Ratio shall be appropriately adjusted at the Effective Time to reflect fully the effect of the Reverse Stock Split.

2.2 Conversion of Capital Stock. As of the Effective Time, by virtue of the Merger and without any action on the part of the holder of any shares of the capital stock of Merger Partner or the holder of any shares of the capital stock of the Transitory Subsidiary:

(a) Capital Stock of the Transitory Subsidiary. Each share of the common stock of the Transitory Subsidiary issued and outstanding immediately prior to the Effective Time shall be converted into and become one fully paid and nonassessable share of common stock, \$0.001 par value per share, of the Surviving Corporation.

(b) Cancellation of Treasury Stock and Public Company Owned Stock. All shares of Merger Partner Common Stock that are owned by Merger Partner as treasury stock or by any wholly owned Subsidiary of Merger Partner and any shares of Merger Partner Common Stock owned by Public Company, the Transitory Subsidiary or any other wholly owned Subsidiary of Public Company immediately prior to the Effective Time shall be cancelled and shall cease to exist and no stock of Public Company or other consideration shall be delivered in exchange therefor.

A-10

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(c) Exchange Ratio for Merger Partner Common Stock. Upon surrender of the certificate representing such share of Merger Partner Common Stock in the manner provided in Section 2.3 and subject to the provisions thereof, each share of Merger Partner Common Stock (other than shares to be cancelled in accordance with Section 2.2(b) and Dissenting Shares) shall be converted into and exchanged for the right to receive a number of shares of Public Company Common Stock equal to the product of (i) 2.3333 multiplied by (ii) the quotient of (A) 43,479,198 divided by (B) the sum of (x) the number of shares of Merger Partner Common Stock outstanding immediately prior to the Effective Time plus (y) the number of shares of Merger Partner Common Stock issuable upon exercise of Merger Partner Stock Options and Merger Partner Warrants outstanding immediately prior to the Effective Time, subject to adjustment as provided in Section 2.1(d) (the Exchange Ratio ). As of the Effective Time, all such shares of Merger Partner Common Stock shall no longer be outstanding and shall automatically be cancelled and shall cease to exist, and each holder of a certificate representing any such shares of Merger Partner Common Stock shall cease to have any rights with respect thereto, except the right to receive the shares of Public Company Common Stock pursuant to this Section 2.2(c) and any cash in lieu of fractional shares of Public Company Common Stock to be issued or paid in consideration therefor upon the surrender of such certificate in accordance with Section 2.3, without interest. For purposes of this Agreement, Dissenting Shares shall mean Merger Partner Common Stock held as of the Effective Time that has not been voted in favor of the adoption of this Agreement and with respect to which appraisal shall have been duly demanded and perfected in accordance with the DGCL and not effectively withdrawn or forfeited prior to the Effective Time.

(d) Unvested Stock. At the Effective Time, any shares of Public Company Common Stock issued in accordance with Section 2.2(c) with respect to any unvested shares of Merger Partner Common Stock awarded to employees, directors or consultants pursuant to any of Merger Partner's plans or arrangements and outstanding immediately prior to the Effective Time shall remain subject to the same terms, restrictions and vesting schedule as in effect immediately prior to the Effective Time, except to the extent by their terms such unvested shares of Merger Partner Common Stock vest at the Effective Time. Copies of the relevant agreements governing such shares and the vesting thereof have been provided or made available to Public Company. All outstanding rights that Merger Partner may hold immediately prior to the Effective Time to repurchase unvested shares of Merger Partner Common Stock shall be assigned to Public Company in the Merger and shall thereafter be exercisable by Public Company upon the same terms and conditions in effect immediately prior to the Effective Time, except that the shares purchasable pursuant to such rights and the purchase price payable per share shall be appropriately adjusted to reflect the Exchange Ratio. Merger Partner shall take all steps necessary to cause the foregoing provisions of this Section 2.2(d) to occur.

2.3 Exchange of Certificates. The procedures for exchanging outstanding shares of Merger Partner Common Stock for Public Company Common Stock pursuant to the Merger are as follows:

(a) Exchange Agent. As of the Effective Time, Public Company shall deposit with BNY Mellon Shareowner Services or another bank or trust company designated by Public Company and reasonably acceptable to Merger Partner (the Exchange Agent ), for the benefit of the holders of shares of Merger Partner Common Stock, for exchange in accordance with this Section 2.3, through the Exchange Agent, (i) certificates representing the shares of Public Company Common Stock (such shares of Public Company Common Stock, together with any dividends or distributions with respect thereto with a record date after the Effective Time, being hereinafter referred to as the Exchange Fund ) issuable pursuant to Section 2.2 in exchange for outstanding shares of Merger Partner Common Stock, (ii) cash in an amount sufficient to make payments for fractional shares required pursuant to Section 2.3(c) and (iii) any dividends or distributions to which holders of certificates that immediately prior to the Effective Time represented outstanding shares of Merger Partner Common Stock (the Certificates ) whose shares were converted pursuant to Section 2.2 into the right to receive shares of Public Company Common Stock may be entitled pursuant to Section 2.3(d).

(b) Exchange Procedures. As soon as reasonably practicable after the Effective Time, the Exchange Agent shall mail to each holder of record of a Certificate (i) a letter of transmittal in customary form (which shall specify that delivery shall be effected, and risk of loss and title to the Certificates shall pass, only upon delivery of the Certificates to the Exchange Agent) and (ii) instructions for effecting the surrender of the Certificates in exchange for certificates representing shares of Public Company Common Stock (plus

A-11

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cash in lieu of fractional shares, if any, of Public Company Common Stock and any dividends or distributions as provided below). Upon surrender of a Certificate for cancellation to the Exchange Agent or to such other agent or agents as may be appointed by Public Company, together with such letter of transmittal, duly executed, and such other documents as may reasonably be required by the Exchange Agent, the holder of such Certificate shall be entitled to receive in exchange therefor a certificate representing that number of whole shares of Public Company Common Stock which such holder has the right to receive pursuant to the provisions of this Article II plus cash in lieu of fractional shares pursuant to Section 2.3(c) and any dividends or distributions then payable pursuant to Section 2.3(d), and the Certificate so surrendered shall immediately be cancelled. In the event of a transfer of ownership of Merger Partner Common Stock which is not registered in the transfer records of Merger Partner, a certificate representing the proper number of shares of Public Company Common Stock plus cash in lieu of fractional shares pursuant to Section 2.3(c) and any dividends or distributions pursuant to Section 2.3(d) may be issued or paid to a person other than the person in whose name the Certificate so surrendered is registered, if such Certificate is presented to the Exchange Agent, accompanied by all documents required to evidence and effect such transfer and by evidence that any applicable stock transfer taxes have been paid. Until surrendered as contemplated by this Section 2.3, each Certificate shall be deemed at any time after the Effective Time to represent only the right to receive upon such surrender the certificate representing shares of Public Company Common Stock plus cash in lieu of fractional shares pursuant to Section 2.3(c) and any dividends or distributions then payable pursuant to Section 2.3(d), as contemplated by this Section 2.3.

(c) No Fractional Shares. No certificate or scrip representing fractional shares of Public Company Common Stock shall be issued upon the surrender for exchange of Certificates, and such fractional share interests shall not entitle the owner thereof to vote or to any other rights of a stockholder of Public Company. Notwithstanding any other provision of this Agreement, each holder of shares of Merger Partner Common Stock converted pursuant to the Merger who would otherwise have been entitled to receive a fraction of a share of Public Company Common Stock (after taking into account all Certificates delivered by such holder and the aggregate number of shares of Merger Partner Common Stock represented thereby) shall receive, in lieu thereof, cash (without interest) in an amount equal to such fractional part of a share of Public Company Common Stock multiplied by the average of the last reported sales prices of Public Company Common Stock at the 4:00 p.m., Eastern time, end of regular trading hours on NASDAQ during the ten consecutive trading days ending on the last trading day prior to the Effective Time.

(d) Distributions with Respect to Unexchanged Shares. No dividends or other distributions declared or made after the Effective Time with respect to Public Company Common Stock with a record date after the Effective Time shall be paid to the holder of any unsurrendered Certificate until such Certificate is surrendered as described in Section 2.3(b), subject to Section 2.3(i). Subject to the effect of applicable laws, following surrender of any such Certificate, there shall be issued and paid to the record holder of the Certificate, at the time of such surrender the amount of dividends or other distributions with a record date after the Effective Time previously paid with respect to such whole shares of Public Company Common Stock, without interest, and at the appropriate payment date, the amount of dividends or other distributions having a record date after the Effective Time but prior to surrender and a payment date subsequent to surrender that are payable with respect to such whole shares of Public Company Common Stock.

(e) No Further Ownership Rights in Merger Partner Common Stock. All shares of Public Company Common Stock issued upon the surrender for exchange of Certificates in accordance with the terms hereof (including any cash or dividends or other distributions paid pursuant to Section 2.3(c) or 2.3(d)) shall be deemed to have been issued (and paid) in full satisfaction of all rights pertaining to such shares of Merger Partner Common Stock, and from and after the Effective Time there shall be no further registration of transfers on the stock transfer books of the Surviving Corporation of the shares of Merger Partner Common Stock that were outstanding immediately prior to the Effective Time. If, after the Effective Time, Certificates are presented to the Surviving Corporation or the Exchange Agent for any reason, they shall be cancelled and exchanged as provided in this Article II, subject to applicable law in the case

of Dissenting Shares.

(f) Termination of Exchange Fund. Any portion of the Exchange Fund that remains undistributed to the holders of Merger Partner Common Stock for 180 days after the Effective Time shall be

A-12

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delivered to Public Company, upon demand, and any holder of Merger Partner Common Stock who has not previously complied with this Section 2.3 shall thereafter look only to Public Company, as a general unsecured creditor, for payment of its claim for Public Company Common Stock, any cash in lieu of fractional shares of Public Company Common Stock and any dividends or distributions with respect to Public Company Common Stock.

(g) No Liability. To the extent permitted by applicable law, none of Public Company, the Transitory Subsidiary, Merger Partner, the Surviving Corporation or the Exchange Agent shall be liable to any holder of shares of Merger Partner Common Stock or Public Company Common Stock, as the case may be, for such shares (or dividends or distributions with respect thereto) delivered to a public official pursuant to any applicable abandoned property, escheat or similar law. If any Certificate shall not have been surrendered immediately prior to such date on which any shares of Public Company Common Stock, and any cash payable to the holder of such Certificate or any dividends or distributions payable to the holder of such Certificate pursuant to this Article II would otherwise escheat to or become the property of any Governmental Entity, any such shares of Public Company Common Stock or cash, dividends or distributions in respect of such Certificate shall, to the extent permitted by applicable law, become the property of the Surviving Corporation, free and clear of all claims or interest of any person previously entitled thereto.

(h) Withholding Rights. Each of Public Company, the Surviving Corporation and the Exchange Agent shall be entitled to deduct and withhold from the consideration otherwise payable pursuant to this Agreement to any holder of shares of Merger Partner Common Stock and any other recipient of payments hereunder such amounts as it reasonably determines that it is required to deduct and withhold with respect to the making of such payment under the Code, or any other applicable provision of law. To the extent that amounts are so withheld by the Surviving Corporation, Public Company or the Exchange Agent, as the case may be, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the holder of the shares of Merger Partner Common Stock or other recipient of payments hereunder in respect of which such deduction and withholding was made by the Surviving Corporation, Public Company or the Exchange Agent, as the case may be.

(i) Lost Certificates. If any Certificate shall have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming such Certificate to be lost, stolen or destroyed and, if required by the Surviving Corporation, the posting by such person of a bond in such reasonable amount as the Surviving Corporation may direct as indemnity against any claim that may be made against it with respect to such Certificate, the Exchange Agent shall issue in exchange for such lost, stolen or destroyed Certificate the shares of Public Company Common Stock and any cash in lieu of fractional shares, and unpaid dividends and distributions on shares of Public Company Common Stock deliverable in respect thereof pursuant to this Agreement.

#### 2.4 Merger Partner Stock Plans and Merger Partner Warrants.

(a) At the Effective Time, each outstanding option to purchase Merger Partner Common Stock ( Merger Partner Stock Options ), whether vested or unvested, and all stock option plans or other stock or equity-related plans of Merger Partner (the Merger Partner Stock Plans ) themselves, insofar as they relate to outstanding Merger Partner Stock Options, shall be assumed by Public Company and shall become an option to acquire, on the same terms and conditions as were applicable under such Merger Partner Stock Option immediately prior to the Effective Time, such number of shares of Public Company Common Stock as is equal to the number of shares of Merger Partner Common Stock subject to the unexercised portion of such Merger Partner Stock Option immediately prior to the Effective Time 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 Merger Partner Stock Option immediately prior to the Effective Time divided by the Exchange Ratio (rounded up to the nearest whole cent); provided that the assumption of each Merger Partner Stock Option pursuant to this Section 2.4(a) shall comply with all requirements of Sections 424 and 409A of the Code and the final Treasury regulations issued thereunder. Such Merger Partner Stock Options shall continue in effect on the same terms and conditions to which they are currently subject (subject to the adjustments required by this



Section 2.4 after giving effect to the Merger).

A-13

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- (b) As soon as practicable after the Effective Time, Public Company shall deliver to the participants in the Merger Partner Stock Plans appropriate notice setting forth such participants' rights pursuant to the Merger Partner Stock Options, as provided in this Section 2.4.
- (c) Public Company shall take all corporate action necessary to reserve for issuance a sufficient number of shares of Public Company Common Stock for delivery upon exercise of the Merger Partner Stock Options assumed in accordance with this Section 2.4. As promptly as practicable after the Effective Time, Public Company shall file a registration statement on Form S-8 (or any successor form) or another appropriate form with respect to the shares of Public Company Common Stock subject to such options and shall use commercially reasonable efforts to maintain the effectiveness of such registration statement or registration statements (and maintain the current status of the prospectus or prospectuses contained therein) for so long as such options remain outstanding.
- (d) Merger Partner shall terminate any employee stock purchase plans in accordance with their terms as of or prior to the Effective Time.
- (e) At the Effective Time, each Merger Partner Warrant outstanding immediately prior to the Effective Time shall be assumed by Public Company and shall become a warrant to acquire, on the same terms and conditions as were applicable under such Merger Partner Warrant, such number of shares of Public Company Common Stock as is equal to the number of shares of Merger Partner Common Stock subject to the unexercised portion of such Merger Partner Warrant immediately prior to the Effective Time 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 Merger Partner Warrant immediately prior to the Effective Time divided by the Exchange Ratio (rounded up to the nearest whole cent) (each, as so adjusted, an Adjusted Warrant). Prior to the Effective Time, Public Company shall take all necessary actions for the assumption of Merger Partner Warrants and their conversion into Adjusted Warrants, including the reservation and listing of Public Company Common Stock in a number at least equal to the number of shares of Public Company Common Stock that will be subject to the Adjusted Warrants.

## 2.5 Dissenting Shares.

- (a) Dissenting Shares shall not be converted into or represent the right to receive Public Company Common Stock unless the stockholder holding such Dissenting Shares shall have forfeited his, her or its right to appraisal under the DGCL or properly withdrawn his, her or its demand for appraisal. If such stockholder has so forfeited or withdrawn his, her or its right to appraisal of Dissenting Shares, then (i) as of the occurrence of such event, such holder's Dissenting Shares shall cease to be Dissenting Shares and shall be converted into and represent the right to receive the Public Company Common Stock issuable in respect of such Merger Partner Common Stock pursuant to Section 2.2(c), and (ii) promptly following the occurrence of such event, Public Company shall deliver to the Exchange Agent a certificate representing the Public Company Common Stock to which such stockholder is entitled pursuant to Section 2.2(c).
- (b) Merger Partner shall give Public Company (i) prompt notice of any written demands for appraisal of any Merger Partner Common Stock, withdrawals of such demands and any other instruments that relate to such demands received by Merger Partner and (ii) the opportunity to direct all negotiations and proceedings with respect to demands for appraisal under the DGCL. Merger Partner shall not, except with the prior written consent of Public Company, make any payment with respect to any demands for appraisal of Merger Partner Common Stock or offer to settle or settle any such demands.

## ARTICLE III

### **REPRESENTATIONS AND WARRANTIES OF MERGER PARTNER**

Merger Partner represents and warrants to Public Company and the Transitory Subsidiary that the statements contained in this Article III are true and correct, except as expressly set forth herein or in the disclosure schedule delivered by Merger Partner to Public Company and the Transitory Subsidiary on the date of this Agreement (the Merger Partner Disclosure Schedule ). The Merger Partner Disclosure Schedule shall

A-14

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be arranged in sections corresponding to the numbered and lettered sections contained in this Article III and the disclosure in any section shall qualify (1) the corresponding section in this Article III and (2) the other sections in this Article III only to the extent that it is reasonably apparent from a reading of such disclosure that it also qualifies or applies to such other sections. For purposes hereof, to the knowledge of Merger Partner and similar expressions mean the knowledge of the persons identified on the Merger Partner Disclosure Schedule for this purpose, as well as any other knowledge which such persons would have possessed had they made reasonable inquiry with respect to the matter in question.

3.1 Organization, Standing and Power. Merger Partner is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as currently conducted and as currently proposed to be conducted, and is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction listed on Section 3.1 of the Merger Partner Disclosure Schedule, which jurisdictions constitute the only jurisdictions in which the character of the properties it owns, operates or leases or the nature of its activities makes such qualification necessary, except for such failures to be so organized, qualified or in good standing, individually or in the aggregate, that have not had, and are not reasonably likely to have, a Merger Partner Material Adverse Effect. For purposes of this Agreement, the term Merger Partner Material Adverse Effect means any material adverse change, event, circumstance or development with respect to, or material adverse effect on, (i) the business, assets, liabilities, condition (financial or other), or results of operations of Merger Partner and its Subsidiaries, taken as a whole, or (ii) the ability of Merger Partner and its Subsidiaries to consummate the transactions contemplated by this Agreement; provided, however, that the following shall not be deemed to be a Merger Partner Material Adverse Effect: any change or event caused by or resulting from (A) changes in prevailing economic or market conditions in the United States or any other jurisdiction in which such entity has substantial business operations (except to the extent those changes have a materially disproportionate effect on Merger Partner and its Subsidiaries as compared to other similarly situated participants in the industries or markets in which Merger Partner and its Subsidiaries operate), (B) changes or events, after the date hereof, affecting the industries in which they operate generally (except to the extent those changes or events have a materially disproportionate effect on Merger Partner and its Subsidiaries as compared to other similarly situated participants in the industries or markets in which Merger Partner and its Subsidiaries operate), (C) changes, after the date hereof, in generally accepted accounting principles or requirements applicable to Merger Partner and its Subsidiaries (except to the extent those changes have a materially disproportionate effect on Merger Partner and its Subsidiaries as compared to other similarly situated participants in the industries or markets in which Merger Partner and its Subsidiaries operate), (D) changes, after the date hereof, in laws, rules or regulations of general applicability or interpretations thereof by any Governmental Entity (except to the extent those changes have a materially disproportionate effect on Merger Partner and its Subsidiaries as compared to other similarly situated participants in the industries or markets in which Merger Partner and its Subsidiaries operate), (E) the execution, delivery and performance of this Agreement or the consummation of the transactions contemplated hereby or thereby or the announcement thereof, or (F) any outbreak of major hostilities in which the United States is involved or any act of terrorism within the United States or directed against its facilities or citizens wherever located. For the avoidance of doubt, the parties agree that the terms material, materially and materiality as used in this Agreement with an initial lower case m shall have their respective customary and ordinary meanings, without regard to the meanings ascribed to Merger Partner Material Adverse Effect in the prior sentence of this paragraph or Public Company Material Adverse Effect in Section 4.1. Merger Partner has provided or made available to Public Company complete and accurate copies of its Certificate of Incorporation and Bylaws and is not in default under or in violation of any provision of either such document.

3.2 Capitalization.

(a) The authorized capital stock of Merger Partner consists of 50,000,000 shares of Merger Partner Common Stock. The rights and privileges of each class of Merger Partner's capital stock are as set forth in Merger Partner's Certificate

of Incorporation. As of the close of business on the business day prior to the date of this Agreement,  
(i) 24,926,150&#1