Trevor Phillips, Ph.D.
President and Chief Executive Officer
Critical Therapeutics, Inc.
60 Westview Street
Lexington, MA 02421

Re: Critical Therapeutics, Inc.

**Registration Statement on Form S-4** 

Filed July 22, 2008 File No. 333-152442

Dear Dr. Phillips:

We have reviewed your filing and have the following comments. Where indicated, we think you should revise your document in response to these comments. If you disagree, we will consider your explanation as to why our comment is inapplicable or a revision is unnecessary. Please be as detailed as necessary in your explanation. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure. After reviewing this information, we may raise additional comments.

Please understand that the purpose of our review process is to assist you in your compliance with the applicable disclosure requirements and to enhance the overall disclosure in your filing. We look forward to working with you in these respects. We welcome any questions you may have about our comments or any other aspect of our review. Feel free to call us at the telephone numbers listed at the end of this letter.

#### FORM S-4

#### General

1. Please note that you are required to file with the Commission any written instructions, scripts, and outlines that will be used by any person that solicit proxies on behalf of the company through personal interview, telephone, or telegram, and all other soliciting material that will be furnished to the security holders of either company.

- 2. Please note that where we provide examples to illustrate what we mean by our comments, they are examples and not complete lists. If our comments are applicable to portions of the filing that we have not cited as examples, please make the appropriate changes in accordance with our comments.
- 3. Please file copies of Cornerstone's material agreements as exhibits to this registration statement, including all material license, collaboration, promotion, manufacturing, supply, distribution, lease, loan and employment agreements. See Item 601(b)(10) of Regulation S-K. In addition, please confirm that you have disclosed the material terms each of these agreements in Cornerstone's Business section, including, but not limited to payment provisions, minimum payments/quantities, the existence of royalty provisions, exclusivity provisions, obligations/rights to defend, and termination provisions. We may have further comments based on your response.
- 4. Please revise your filing with updated interim financial information through the period ended June 30, 2008.

Questions and Answers about the Special Meeting and the Merger, page v

### General

- 5. It is inappropriate to repeat information in the Q&A and the summary. We note that the Q&A section addresses many of the same topics discussed in the summary section. Please revise to eliminate unnecessary repetition. For example,
  - Summary of the merger;
  - Reasons for the merger;
  - Merger consideration;
  - Conditions to the completion of the merger;
  - Percentage of ownership after the merger;
  - Stockholder agreements;
  - Management following the merger;
  - Board of directors following the merger;
  - Tax considerations;
  - Regulatory approvals; and
  - Appraisal rights.

For purposes of eliminating redundancies and grouping like information together, view your Q&A and summary section as one section. We suggest you consider placing procedural related information in the Q&A and substantive information in the summary.

### Summary, page 1

# The Companies, page 1

6. Please revise your disclosure in this section to identify any products that are being sold commercially and whether those products are approved by the FDA for each of Critical Therapeutics and Cornerstone. In addition, please also identify any major pipeline products for each of the companies and indicate the current stage of development (for example, preclinical, Phase I, Phase II, Phase III trials).

### Reasons for the Merger, page 2

7. Please expand your disclosure to describe under separate subheadings the business reasons for the merger transaction from both Critical Therapeutics' and Cornerstone's perspective. You should discuss Critical Therapeutics' perspective in addition to Cornerstone's perspective because the stockholders of Cornerstone will become stockholders of Critical Therapeutics if they approve the merger transaction. If the managements of Critical Therapeutics and/or Cornerstone considered the development programs and products of each other and how these would intersect or other factors such as financial or technical resources, please also describe such considerations.

#### Overview of Merger Agreement, page 2

#### Merger Consideration, page 2

8. Where you describe the respective approximate ownership percentages of the Critical Therapeutics and Cornerstone stockholders, please clarify whether or not these percentages include shares issuable in the merger to the Cornerstone noteholders.

## Conditions to Completion of the Merger, page 2

9. We note that you state that one of the conditions to the merger is the receipt of all authorizations, consents, orders or approvals of any governmental entity in connection with the consummation of the merger. Please revise your disclosure to state the material specific authorizations, consents, orders or approvals which either company must seek to consummate the merger. It appears from your disclosure on pages vi and 6 that this is limited to the compliance with federal and state securities laws.

# Termination of the Merger Agreement, page 3

10. Please revise your disclosure to briefly summarize the circumstances in which either Critical Therapeutics or Cornerstone can terminate the merger agreement.

## Stockholder Agreements and Noteholder Agreement, page 3

- 11. Please revise your disclosure here and on pages 106 and 129 to state the aggregate percentage of stock held by the Cornerstone stockholders which entered into these stockholder agreements.
- 12. Similarly, please state here and on pages 106 and 129 the approximate percent of Cornerstone outstanding stock that will be held by Carolina Pharmaceuticals after the conversion of the note.

# <u>Interests of Critical Therapeutics' Directors and Executive Officers, page 5</u> <u>Interests of Cornerstone's Directors and Executive Officers, page 5</u>

- 13. Please revise your disclosure here and provide more detail in the risk factor on page 18 to briefly summarize and quantify the conflicts or differing interests of each of the directors and executive officers of each company as compared to those of the respective stockholders of that company. For example,
  - For the executive officers and directors of Critical Therapeutics, please include the aggregate amount of cash and other benefits upon a change of control and upon a termination in connection with a change of control.
  - For the executive officers and directors of Cornerstone, please disclose here the approximate percent of shares of the combined company they will hold and have options to acquire following the merger. You should provide this disclosure for each of these persons in the section starting on page 104.
  - Please also disclose the salaries of the executive officers of the combined company following the merger.
  - Please also briefly describe the treatment of the note with Carolina Pharmaceuticals and disclose the percentage of Carolina Pharmaceuticals which Mr. Collard owns.
- 14. Please clarify whether any of Critical Therapeutics' directors and executive officers will continue his or her service with the combined company.
- 15. Please disclose the aggregate percentage of outstanding shares of Cornerstone which are held by Cornerstone's directors, executive officers and their affiliates. See Item 3(h) of Form S-4.

# Stock Options and Warrants, page 5

- 16. Please revise to disclose the number of shares of Cornerstone common stock underlying the outstanding stock options, warrants and other rights to purchase or acquire the capital stock of Cornerstone outstanding prior to the merger.
- 17. Please revise here and throughout to clarify whether or not the stock options and warrants will be adjusted consistent with the exchange ratio.

## Regulatory Approvals, page 6

18. You state here that as of the date hereof, the registration statement has not become effective. Presumably, you will not mail the proxy statement to Critical Therapeutics stockholders or deliver the prospectus to Cornerstone stockholders until after effectiveness. Please confirm whether or not this is the case and supplementally tell us your plans as to timing regarding these issues.

### Risk Factors, page 5

19. Please expand your disclosure to identify some of the key risks relating to the merger.

# Appraisal Rights, page 6

- 20. Please revise your disclosure to indicate which Cornerstone stockholders are entitled to appraisal rights.
- 21. It appears from your disclosure on page 3 that the merger is conditioned upon not more than 5% of Cornerstone's stockholders seeking appraisal rights. If true, please revise your disclosure here and on page 112 to disclose this condition.

### Risk Factors, page 17

## Risks Related to the Merger, page 17

## <u>General</u>

22. We note your disclosure on page 19 that the company discontinued sales of ZYFLO in February 2008 and has been having supply chain issues with ZYFLO CR. We also note that the merger is conditioned upon the continued commercial availability of Critical Therapeutics' products, ZYFLO CR or ZYFLO. Please consider whether you should revise your disclose in this subsection to add a separate risk factor which discusses the relevant risks to the merger.

# "If the proposed merger with Cornerstone is not consummated..." page 17

- 23. This risk factor focuses mainly on the risks to Critical Therapeutics stockholders if the merger does not close. Hence, it is for the most part a list of reasons stockholders should vote to approve the proposals the board and management have proffered. While this risk factor discusses some issues regarding the possible merger, these issues should not be the emphasis of the risk factors section or part of the first or most prominent risk factors. Rather, the risk factors section should focus primarily, first and foremost on the risks to Critical Therapeutics and Cornerstone stockholders if the merger is completed. We note that the highlighted risks are probably not that relevant, if at all, to Cornerstone stockholders if the merger does not close. For Critical Therapeutics stockholders, the foremost risks you should highlight should be the risks that would ensue if they approve the proposals and the merger closes. Accordingly, you should reorder and revise all of your risk factors to highlight the most significant risks.
- 24. To the extent that you feel these any of the risks would be better described in a separate risk factor, please revise your disclosure to separately discuss these risks. To extent these are not really risks, but reasons to vote in favor of the merger, consider whether they should be highlighted at all.
- 25. Please expand your first bullet point in this risk factor to state the approximate amount of Critical Therapeutics' expenses to date in connection with this merger.
- 26. Please clarify that if stockholders do not approve the proposals and this causes the merger not to close, that the termination fee will not have to be paid.

# "Some of Critical Therapeutics' and Cornerstone's officers and directors have conflicts of interest..." page 18

27. Please revise to quantify the compensation or other benefits that the officers and directors will receive in connection with the merger, including any expected amount of cash payable (including retention and severance payments). Additionally, please disclose the weighted average exercise price or the range of exercise prices of stock options that will accelerate in connection with the merger.

# "The merger may be completed even though material adverse change..." page 18

28. Please state briefly and whether under some circumstances the closing conditions regarding a material adverse change may be waived by the parties without seeking further stockholder approval.

"The market price of the combined company's common stock..." page 18

29. We note that Critical Therapeutics' stock price has declined dramatically since the parties entered into the merger agreement on May 1, 2008. Please highlight that price decline here.

"Critical Therapeutics' and Cornerstone's stockholders may not realize a benefit from the merger commensurate with the ownership dilution..." page 19

30. Please expand this factor to quantify the percentage of ownership dilution that the stockholders of each of Critical Therapeutics and Cornerstone may experience from the merger. This should include, for Critical Therapeutics, highlighting dilution regarding book value per share, and for Cornerstone, highlighting dilution to earnings per share.

"During the pendency of the merger, Critical Therapeutics and Cornerstone may not be able to enter into a business combination with another party..." page 19

31. You state, "As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors." The risk you highlight regarding the restrictive covenants in the merger agreement exist regardless of whether the merger closes or not. Therefore, you should consider deleting this sentence.

Risks Related to Critical Therapeutics, page 19

"Critical Therapeutics' business depends heavily on the commercial success of ZYFLO CR." page 19

32. Please expand your disclosure to explain how resuming the supply of ZYFLO in August 2008 will "help manage the potential impact to patients of the supply chain issues for ZYFLO CR." In addition, please revise your disclosure to briefly discuss the ZYFLO CR supply chain issues which you discuss on page 22.

"If ZYFLO does not achieve market acceptance, Critical Therapeutics may not be able to generate significant revenues...." page 20

33. We note that you have included a discussion of the adverse effects of ZYFLO and ZYFLO CR in this risk factor. Please separate this discussion into an appropriately subtitled risk factor. In addition, please revise your disclosure in that risk factor to discuss all the related risks.

# "A failure to maintain appropriate inventory levels could harm Critical Therapeutics' reputation..." page 22

34. We note that you expect that your inventory levels could increase substantially in the future as a result of your minimum purchase obligations. Please revise your disclosure in this risk factor and in your business section to disclose the amount of these minimum purchase obligations. Please similarly revise the risk factor relating to Cornerstone on page 54.

# "If the market is not receptive to Critical Therapeutics' product candidates..." page 23

35. Please revise this risk factor to identify your product candidates under development. If applicable, please revise the risk factor to provide examples of problems with each of these factors and/or issues that the company has encountered in connection with the product candidates. Please similarly revise the risk factor relating to Cornerstone on the top page 56.

# "Critical Therapeutics identified a material weakness in its internal control over financial reporting..." page 26

36. Please revise your disclosure to state what the material weakness in internal controls related to.

# "Critical Therapeutics' business has a substantial risk of product liability claims." page 31

- 37. Please provide appropriate disclosure, if applicable, about known pending threats of product liability claims. Please similarly revise the risk factor relating to Cornerstone on page 55.
- 38. Please disclose whether there is a per claim limit and, if material, please disclose the cost of such product liability coverage. Please similarly revise the risk factor relating to Cornerstone on page 55.

# "If Critical Therapeutics does not obtain the regulatory approvals or clearances required to market and sell Critical Therapeutics' product candidates..." page 31

39. This risk factor appears to cover two separate risks: (1) your need to obtain regulatory approvals and (2) your limited experience in obtaining such approvals. Please revise your disclosure to include two separate risk factors, with appropriate subtitles. Please similarly revise the risk factor relating to Cornerstone on page 58.

# "If Critical Therapeutics is unable to enter into additional collaboration agreements..." page 41

40. We note that you state that you have determined to seek to enter into collaboration arrangements with respect to the development of your alpha-7 product candidates and your zileuton injection product candidate. Please revise your disclosure to state whether you have commenced discussions that are at the term sheet or similar stage and discuss the progress of any negotiations.

# "Critical Therapeutics will require substantial additional capital to fund its operations." page 44

41. This risk factor appears to cover three separate risks: (1) the need for additional capital to fund operations, (2) the possible sale of the your securities, which may significantly dilute existing shareholders, and (3) the substantial doubt about your ability to continue as a going concern. Please revise your disclosure to include three separate risk factors, with appropriate subtitles. Please similarly revise the risk factor relating to Cornerstone on page 71 which includes the risks discussed in (1) and (2) above and please add a separate risk factor relating to the fact Cornerstone's financial statements assume that it will continue as a going concern.

## "Critical Therapeutics' stock price is subject to fluctuation..." page 46

42. To illustrate the fluctuations of your share price, please provide a range of Critical Therapeutics' share price during the past year. Please note that it is not necessary to provide a market price table as the disclosure of the high and low price during this time period is sufficient. You should also note the substantial drop in the share price since May 1, 2008.

# "Insiders have substantial control over Critical Therapeutics and could delay or prevent a change in corporate control..." page 48

43. Please revise your disclosure in this risk factor and the risk factor which immediately follows, "Anti-takeover provisions in Critical Therapeutics' charter documents...," to clarify how such risks currently apply to Critical Therapeutics and given the pending merger. Please include in your revised disclosure the percentage of Critical Therapeutics' stockholders that have signed stockholder agreements to vote their shares in favor of the merger. Please similarly revise the risk factor relating to Cornerstone on page 75.

# Risks Related to Cornerstone, page 49

#### General

44. To the extent applicable, please review and revise your disclosure in this section in accordance with the comments above in the section "Risks Related to Critical Therapeutics."

"Cornerstone's strategy of obtaining, through acquisitions and in-licenses, rights to products..." page 50

45. We note that you state that you are seeking to acquire rights to products and product candidates. Please revise your disclosure to state whether you have commenced discussions that are at the term sheet or similar stage and discuss the progress of any negotiations.

"If Cornerstone's third-party manufacturers and packagers do not obtain the necessary quota for procurement of controlled substances..." page 55

46. Please revise your disclosure here on and page 182 to name the third-party manufacturers and packagers who obtain the quotas from the DEA. To the extent you are substantially dependent on such entities, please file copies of the agreements as material contracts pursuant to Item 601(b)(10) of Regulation S-K.

"If clinical trials for Cornerstone's product candidates are delayed..." page 56

47. Please revise this risk factor to disclose briefly and provide more detail in Business section regarding each of Cornerstone's ongoing and currently planned clinical trials. In addition, please revise your disclosure to disclose any problems that the company has experienced in the past two years with the factors listed in this risk factor.

"Some of Cornerstone's specialty pharmaceutical products are now being marketed without approved NDAs or ANDAs." page 59

48. Please revise your disclosure to include the amount and percentage of your net sales of your products as of the year ended December 31, 2008 and your quarter ended June 30, 2008 to which this risk factor relates. Please disclose your net sales of these products as an aggregate of each class of drugs that Cornerstone currently sells products.

"Cornerstone's sales depend on payment and reimbursement from third-party payors..." page 60

49. Please revise your disclosure here and in the Business section on page 181 to disclose whether each of Cornerstone's current products are covered under Medicare, Medicaid and private insurance plans.

# "If Cornerstone is unable to obtain and maintain protection for the intellectual property..." page 64

- 50. We note that on page 201 you disclose that an examiner at the U.S. Patent and Trademark Office has rejected claims of the U.S. Patent 6,270,796. Please revise your disclosure in this risk factor to discuss the risks involved with that reexamination and if and how it effects the potential re-examination of U.S. Patent 6,843,372.
- 51. We note that you disclose that the SPECTRACEF composition of matter patent expires in April 2009. Please consider whether you should add a risk factor which addresses this risk. If you do not feel that a risk factor is appropriate, please supplementally provide us with your analysis which supports this conclusion.

# "If Cornerstone infringes or is alleged to infringe intellectual property rights of third parties..." page 67

52. To the extent you have experienced problems with the risks you discuss in this risk factor, please revise your disclosure to discuss.

# "Cornerstone uses third parties to manufacture all of its products and product candidates." page 68

53. Please name the single-source suppliers which you discuss in this risk factor.

## "Cornerstone relies on third parties to conduct its clinical trials..." page 69

54. Please identify the third parties that Cornerstone relies on for conducting its clinical trials. Also, to the extent Cornerstone has any agreements with such parties that are not already described in the Business section and filed as exhibits, please revise to describe and file copies of the agreements.

# Risks Related to the Combined Company, page 75

"Critical Therapeutics and Cornerstone may not realize the benefits they expect from the merger." page 75

- 55. Please expand your risk factor to discuss how long you estimate the integration period will last, what the material costs of the integration will be, and whether any third party has indicated its intention to terminate a material agreement or to defer or delay a decision in response to the merger.
- 56. This risk factor appears to cover two separate risks: (1) the risks relating to the difficulty and cost of integrating the two companies, and (2) the risks relating to not achieving the integration benefits that the two companies currently anticipate. Please revise your disclosure to include two separate risk factors, with appropriate titles.

## Forward-Looking Statements, page 79

57. We note the statement that the proxy statement/prospectus includes forward-looking statements within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. As Cornerstone is not currently a U.S. reporting company, Cornerstone is not eligible for the safe harbor. Please revise to clarify that the safe harbor does not apply to forward-looking statements relating to Cornerstone.

#### The Merger, page 84

#### General

58. Please provide disclosure with respect to the background of and the reasons for the merger from Cornerstone's perspective. The discussion should be comparable to the disclosure you have in this section for Critical Therapeutics. At a minimum the disclosure should include what alternatives Cornerstone considered, a description of board meetings and other events leading up to the transaction, and the reasons Cornerstone decided to engage in the transaction.

#### Background of the Merger, page 84

59. We note that the Critical Therapeutics' board engaged Lazard in September 2006 and then re-engaged Lazard in October 2007 to assist Critical Therapeutics in considering a potential strategic alternative. Please revise your disclosure regarding both of the engagements to disclose the instructions and limitations provided to Lazard in its search.

- 60. We note the reference to presentation, discussion or report held with or presented by an outside party in your proxy statement/prospectus. Information about any reports, opinions or appraisals that are materially related to the transaction and referred to in the proxy statement/prospectus is required to be disclosed and filed as an exhibit. See Items 4(b) and 21(c) of Form S-4. We note that many of the descriptions of the meetings are vague. Please consider the need to provide additional disclosure to more specifically describe the information discussed at the meetings and file copies of such presentations or reports held for our review. For example:
  - At the November 10, 2007 meeting, you disclose that "the board was briefed on the ongoing process to identify possible strategic transactions." Please revise to disclose the information presented by Lazard to the Critical Therapeutics board.
  - At the March 20, 2008 meeting, you disclose that "Lazard provided an update on the status of the strategic review process and potential transaction with Cornerstone." Please revise to disclose what information was presented by Lazard.
  - At the March 31, 2008 meeting, please provide more information regarding the other potential strategic transaction candidates.
  - At the April 8 and 9, 2008 meetings, please provide more information regarding the financial models for each company and the pro forma models that were discussed.
  - At the April 30, 2008 and May 1, 2008 meetings, please provide more information regarding the financial aspects of the merger by Lazard. In addition, please provide us with a copy of Lazard's board book or similar summary of its analysis that was presented to the Critical Therapeutics board.
- 61. Please expand the description of the electronic data room created by Critical Therapeutics that was available to interested companies. For example, what information was in the data room? To whom was the data room made available and how many companies viewed the data room?
- 62. We note that Critical Therapeutics considered potential business combinations with several companies. Please expand your discussion regarding Companies X, Y and Z to disclose the size of the companies and their respective relevant attributes and the various types of strategic transactions that were discussed with these companies.

- 63. Please disclose when Cornerstone first met with its financial advisor and when that advisor was formally engaged.
- 64. Please explain how the consideration was determined by Critical Therapeutics and Cornerstone. Please disclose the terms as initially proposed and describe changes to the terms during the course of the negotiations. Please also disclose how this consideration compared to that proposed and considered by the other potential reverse merger candidates.

## Critical Therapeutics' Reasons for the Merger, page 92

65. On page 94, please specify the circumstances in which Critical Therapeutics would need to pay the termination fee.

# Opinion of Critical Therapeutics' Financial Advisor, page 95

66. Please revise your disclosure in your second paragraph to clarify that your disclosure summarizes all material terms of Lazard's opinion.

#### Discounted Cash Flow Analysis, page 97

67. Please expand your disclosure to explain how the implied per share values disclosed were derived from the estimated terminal values. Consider providing tabular disclosure. Similarly, please revise the Critical Therapeutics' analyses as appropriate.

# Selected Publicly Traded Companies Analysis, page 97

- 68. Please disclose the market value, enterprise value, and the multiples for each of the comparable companies selected for review in the analyses.
- 69. Please explain why Lazard chose to apply the 15% discount to account for the fact that Cornerstone is not a publicly traded company.

### Miscellaneous, page 99

- 70. We note that your disclosure in this section of the proxy statement/prospectus does not provide a quantitative description of the fees paid or to be paid to Lazard. Please revise to quantify the fees and expenses Lazard is entitled to upon consummation of the merger and the amount of that fee that is contingent on the consummation of the merger.
- 71. Please disclose the amount of the fee that was paid in (a) 2007 to Lazard as exclusive financial advisor to Critical Therapeutics in connection with the

licensing transaction and (b) 2006 to Lazard Capital Markets LLC as sole placement agent in an equity offering.

<u>Interests of Critical Therapeutics' Directors and Executive Officers in the Merger, page</u> 100

## Cash Bonus Awards Upon a "Change in Control", page 102

72. Please file a copy of this bonus plan as an exhibit.

## Noteholder Agreement with Carolina Pharmaceuticals, page 106

73. Please revise your disclosure here and on page 260 to state the specific percentage of voting shares of Carolina Pharmaceuticals that are held by Mr. Collard.

#### Material U.S. Federal Income Tax Consequences of the Merger, page 109

74. Please revise the last paragraph of this section to remove the limitation that it is a summary of "certain" U.S. Federal income tax consequences. Rather, you should state and ensure that you have summarized all material tax consequences. Similarly, please revise page 136.

# Appraisal Rights, page 112

75. Please revise your disclosure in the second paragraph of this section to clarify that this section summarizes all the material terms of a Cornerstone stockholder's appraisal rights. Similarly, please revise the first paragraph on page 115 regarding the merger agreement.

### Matters Being Submitted to a Vote of Critical Therapeutics' Stockholders, page 130

## Proposal 2: Approval of the Reverse Stock Split, page 130

- 76. Please revise your disclosure in this section to provide tabular disclosure of the following information prior to and after the merger assuming both the low end and the high end of the reverse split range:
  - the number of shares issued and outstanding,
  - the number of shares reserved for issuance, and
  - the number of shares authorized but neither issued nor reserved for issuance.

Please also disclose the number of shares you expect to issue in the merger, assuming both the low end and the high end of the reverse split range.

# Critical Therapeutics' Business, page 138

# Collaborations, page 147

77. Revise your disclosure of your agreement with DEY and MedImmune to include a description of all of your rights and obligations, the performance period, all deliverables including your obligation to participate in a joint commercial committee, and the contractual cash flows as stipulated in the agreements in a tabular format. Include a description in your MD&A and in the notes to the consolidated financial statements of the revenue recognition method you employ for each deliverable and the basis for using each revenue recognition method. For example, disclose your method of amortizing the deferred co-promotion fees.

## Cornerstone's Business, page 166

# Acquire Rights to Under-Promoted, Patent-Protected, Branded Respiratory Pharmaceutical Products, page 167

78. Please revise your disclosure to list the eight marketed product lines which you have acquired. Please also disclose whether any of these products are not generating revenues.

# Marketed Products, page 168 Other Products, page 172

- 79. Please revise your disclosure for each of your marketed products and other products discussed on pages 168 through 174 to disclose whether these products have been approved by the FDA and if not, why not.
- 80. Please disclose how Cornerstone acquired the rights to DECONSAL, EXTENDRYL and APAP 500.

#### SPECTRACEF Line Extensions, page 175

#### Proprietary Rights, page 177

81. Please revise your disclosure to state Cornerstone's rights to market and development these line extensions under its licensing agreement with Meiji.

# Other Product Candidates, page 177

# <u>Hydrocodone Cough Suppressant Product Candidates — CBP 067 and CBP 069, page 178</u>

82. Please clarify what company owns the rights to Tussionex.

# Intellectual Property, page 182

#### Patents, page 183

83. Please revise your disclosure to include in tabular format the patents and patent applications which Cornerstone owns or licenses. Please include the patent number, the name of the patent, the Cornerstone product that patent relates to, the jurisdiction which granted the patent, the expiration date and whether Cornerstone owns or licenses the patent.

# Competition, page 189

84. Please revise your disclosure to list your competitors for each of your products or provide a reference to the list you have provided in the risk factor on page 53.

#### Critical Therapeutics' Management's Discussion and Analysis..., page 203

85. We note that on page 34 you disclose that in connection with the approval of the NDA for ZYFLO CR, 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. It does not appear that you have conducted such a trial to date. Please consider whether you should discuss the need to conduct this trial in this section.

## Financial Operations Overview, page 204

## Critical Accounting Policies, page 208

# Revenue Recognition, page 208

86. Please tell us why recognition of product revenues upon shipment to third parties is considered appropriate. Explain how, at the time of shipment, these revenues are considered realized or realizable and earned. Refer to the specific section in SAB 104 that provided the guidance for the method you used.

- 87. Please provide a roll forward of each item that reduces your gross revenue such as reserves for returns and allowances and for chargebacks for the periods presented to disclose:
  - Beginning balance
  - Current provision related to sales made in current period,
  - Current provision related to sales made in prior periods,
  - Actual returns or credits in current period related to sales made in current period,
  - Actual returns or credits in current period related to sales made in prior periods, and
  - Ending balance.

Cornerstone's Management's Discussion and Analysis of Financial Condition and Results of Operations, page 231

Critical Accounting Estimates, page 238

#### Revenue Recognition, page 238

- 88. Revise your roll forward of the items that reduce gross revenue such as reserves for returns and allowances and for chargebacks to disclose:
  - Beginning balance
  - Current provision related to sales made in current period,
  - Current provision related to sales made in prior periods,
  - Actual returns or credits in current period related to sales made in current period,
  - Actual returns or credits in current period related to sales made in prior periods, and
  - Ending balance.

# Liquidity and Capital Resources, page 248

89. Please revise your discussion of cash flows, especially of your operating cash flows, to specifically address your sources and uses of cash in addition to your current disclosures. Please refer to Section IV.B. of Financial Reporting Release 72.

Management Following the Merger, page 256

Certain Relationships and Related Transactions, and Director Independence, page 260

90. We note your disclosure on pages F-77 and F-100 regarding the unpaid advances to Mr. Collard. Please revise your disclosure in this section to include a

description of the advances. In addition, please disclose whether the company has a specific policy or procedure with regard to the terms, amount and frequency of the advances.

91. We also note that you disclose information regarding a license to Auriga Laboratories in this same related party footnote. Please either disclose this as a related party transaction or provide us with your analysis as to why you believe this is not a related party transaction.

## Executive Compensation and Other Information, page 261

# Base Salary, page 262

- 92. It appears from your disclosure in footnote 2 to the 2007 Grants of Plan-Based Awards table on page 265 that Mr. Lutz's 2007 salary was increased to be \$230,000 rather than \$204,000. Please revise your disclosure here and in the Summary Compensation Table on page 264 to remove this inconsistency.
- 93. It appears from your disclosure that Ms. Baldwin's base salary increase for 2007 was based on her achievement of her 2006 performance goals. If true, please revise your disclosure to disclose Cornerstone's specific net revenue targets and each of the targeted budget levels as it appears these are material to her 2007 compensation. See Item 402(b)(2)(v) and Instruction 2 to Item 402(b). To the extent you believe that disclosure of these targets is not required because it would result in competitive harm such that the targets could be excluded under Instruction 4 to Item 402(b) of Regulation S-K, please provide on a supplemental basis a detailed explanation for such conclusion. Please also note that to the extent that you have an appropriate basis for omitting the specific targets, you must discuss how difficult it would be for the named executive officer or how likely it will be for you to achieve the undisclosed target levels or other factors. General statements regarding the level of difficulty, or ease, associated with achieving performance goals either corporately or individually are not sufficient.

## Annual Bonuses, page 263

- 94. Please provide us more information regarding the interaction between the individual goals which are established on a quarterly basis for each executive officer and the amount of such officer's annual bonus.
- 95. It appears that all of your executive officers received at least the full amount of their targeted annual bonus. If true, please revise your disclosure to disclose this fact.

## Summary Compensation Table, page 264

96. Please revise your table to include a footnote disclosing all assumptions made in the valuation. See the Instruction to Item 402(c)(2)(v) and(vi) of Regulation S-K.

# Unaudited Pro Forma Condensed Combined Financial Statements, page 274

## Unaudited Pro Forma Condensed Combined Statement of Operations, page 277

97. Please disclose the effect of the reverse stock split on the calculation of the basic and diluted loss per share and on the pro forma weighted average share outstanding included on the face of these statements and disclose this information elswhere in the filing as appropriate.

## Notes to Unaudited Pro Forma Condensed Comined Financial Statemetns, page 278

98. Please revise your discussion to address the treatment of the cash bonus awards due to your executive officers upon change in control.

## (2) Purchase Price, page 278

99. Please disclose the methodology used to establish the fair value of the inventory acquired. Disclose the components of the inventory acquired.

#### (3) Pro Forma Adjustments, page 279

100. Please tell us why your pro forma adjustment E "to eliminate deferred copromotion fees ... " is considered factually supportable. Please remove the effect of this pro forma adjustment from the pro forma financial statements if you conclude that the adjustment is not factually supportable.

## Principal Stockholders of Critical Therapeutics, page 290

- 101. Please update your principal stockholders tables to be as of the most recent practicable date.
- 102. Please disclose the name of the natural person who has voting control of the shares owned by MedImmune Ventures, Inc. Similarly, please revise Cornerstone's and the combined company's beneficial ownership tables on pages 293 and 295 to provide footnote references of the natural persons who have voting control of the various entities listed in the tables.

# Consolidated Financial Statements, Critical Therapeutics, Inc.

103. Please present the effect of the reverse stock split in pro forma EPS on the face of the financial statements and in other parts of the filing as appropriate or tell us why the current presentation is appropriate. Appropriate discussion of the split should be included in MD&A, including pro forma effects of the split.

# Consolidated Financial Statements, Cornerstone Biopharma Holdings, Inc

## Consolidated Statement of Operations, page F-54

104. Please disclose basic and diluted earnings per share and weighted average number of common shares outstanding information on the face of your statements of operations and disclose your earnings per share calculation in the notes to the financial statements.

#### Consolidated Statements of Cash flows, page F-56

105. We note that you included advances to related parties within operating and investing activities. Please revise the presentation to present these amounts on a gross basis in financing activities or explain the basis for your current presentation. Refer to paragraphs 18-20 of SFAS 95.

#### Note 1: Summary of Significant Accounting Policies, page F-58

#### Product Rights, page F-61

- 106. Please tell us why you have not classified the amortization of product rights as cost of product sales.
- 107. You state that amortization of product rights begins once FDA approval has been obtained and commercialization of the product begins which appears to defer amortization. Please tell us you basis for deferring amortization.

#### Stock-Based Compensation, page F-63

- 108. Please provide additional support clarifying the adequacy of the 68% volatility rate used. In order to help us evaluate your analysis, include the names of the companies that you used as comparables. In addition, revise your disclosures to include all of the disclosures required by paragraph A240(e)(2)(b) of SFAS 123(r).
- 109. Please disclose your accounting for the series of modifications to the terms of your debt outstanding under the line of credit agreement and tell us how your

accounting complies with the provisions of paragraph 16 of SFAS 140 and EITF 96-19.

# Note 6: Stockholder's Deficit, page F-71

- 110. Please disclose in the financial statements, at a minimum, the following information for all equity instruments (i.e. options, warrants, restricted common stock etc.) granted to employees <u>and</u> non-employees during the periods presented:
  - a. For each grant date, the number of options or shares granted, the exercise price, the fair value of the common stock, and the intrinsic value, if any, per option
  - b. Whether or not the valuation used to determine the fair value of the equity instruments was contemporaneous or retrospective
  - c. Whether or not the valuation specialist was a related party

For equity issuances subsequent to the balance sheet date, provide us the above information and consider additional disclosure in the filing, if material.

- 111. If the valuation of equity instruments was not performed contemporaneously, please disclose in the Management's Discussion and Analysis the following information relating to your issuances of equity instruments:
  - a. A discussion of significant factors, assumptions, and methodologies used in determining fair value.
  - b. A discussion of each significant factor contributing to the difference between the fair value as of the date of each grant and the and fair value as of the date of your response or if a contemporaneous valuation by an unrelated valuation specialist was obtained subsequent to the grants, the fair value as determined by that valuation.
  - c. The valuation alternative selected and the reason management chose not to obtain a contemporaneous valuation by an unrelated valuation specialist.
  - d. Disclose the intrinsic value of outstanding vested and unvested options based on and fair value as of the date of your response and the options outstanding as of the most recent balance-sheet date presented.

#### Annex B

112. Please revise your Certificate of Amendment of your Amended and Restated Certificate of Incorporation filed as Annex B, to clarify what each of the footnotes relate to.

### **Exhibits**

113. Please have Wilmer Cutler Pickering Hale and Dorr LLP and Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P. each revise their respective tax opinions clearly state that the disclosure in the registration statement is their respective opinion, rather than stating that it "is correct in all material respects."

\* \* \*

As appropriate, please amend your registration statement in response to these comments. You may wish to provide us with marked copies of the amendment to expedite our review. Please furnish a cover letter with your amendment that keys your responses to our comments and provides any requested information. Detailed cover letters greatly facilitate our review. Please understand that we may have additional comments after reviewing your amendment and responses to our comments.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes all information required under the Securities Act of 1933 and that they have provided all information investors require for an informed investment decision. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event the company requests acceleration of the effective date of the pending registration statement, it should furnish a letter, at the time of such request, acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

In addition, please be advised that the Division of Enforcement has access to all information you provide to the staff of the Division of Corporation Finance in connection with our review of your filing or in response to our comments on your filing.

We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. We will act on the request and, pursuant to delegated authority, grant acceleration of the effective date.

We direct your attention to Rules 460 and 461 regarding requesting acceleration of a registration statement. Please allow adequate time after the filing of any amendment for further review before submitting a request for acceleration. Please provide this request at least two business days in advance of the requested effective date.

You may contact Ibolya Ignat at (202) 551-3656 or Joel Parker at (202) 551-3651 if you have questions regarding comments on the financial statements and related matters. Please contact Jennifer Riegel at (202) 551-3575 or me at (202) 551-3715 with any other questions.

Sincerely,

Jeffrey Riedler Assistant Director

cc: Steven D. Singer, Esq.
Michael J. LaCascia, Esq.
Brian A. Johnson, Esq.
Wilmer Cutler Pickering Hale and Dorr LLP
399 Park Avenue
New York, NY 10022