CRITICAL THERAPEUTICS INC
Form 425
May 09, 2008

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Subject Company: Critical Therapeutics, Inc.
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This filing consists of the textual representation of a transcript of a webcast conference call held on May 8, 2008 at which management of Critical Therapeutics, Inc. (the Company) presented prepared remarks regarding the Company s financial results for the three months ended March 31, 2008, ongoing business matters, including with respect to the supply chain for ZYFLO CR™ (zileuton) extended-release tablets and a reduction in the Company s workforce, and the status of the Company s proposed transaction with Cornerstone BioPharma Holdings, Inc. (Cornerstone) pursuant to the Agreement and Plan of Merger entered into by and among the Company, Neptune Acquisition Corp., a wholly owned subsidiary of the Company, and Cornerstone on May 1, 2008 (the Merger Agreement).

IMPORTANT ADDITIONAL INFORMATION WILL BE FILED WITH THE SEC

The Company plans to file with the U.S. Securities and Exchange Commission (SEC) a Registration Statement on Form S-4 and file with the SEC and mail to its stockholders a Proxy Statement/Prospectus in connection with the proposed transaction with Cornerstone. The Registration Statement and the Proxy Statement/Prospectus will contain important information about the Company, Cornerstone, the transaction and related matters. Investors and security holders are urged to read the Registration Statement and the Proxy Statement/Prospectus carefully when they are available.

Investors and security holders will be able to obtain free copies of the Registration Statement and the Proxy Statement/Prospectus and other documents filed with the SEC by the Company through the web site maintained by the SEC at www.sec.gov.

In addition, investors and security holders will be able to obtain free copies of the Registration Statement and the Proxy Statement/Prospectus from the Company by contacting Critical Therapeutics, Inc., Attn: Chief Financial Officer, 60 Westview Street, Lexington, MA 02421.

The Company, and its directors and executive officers, may be deemed to be participants in the solicitation of proxies in respect of the transactions contemplated by the Merger Agreement. Information regarding the Company s directors and executive officers is contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2007, as amended, and its proxy statement dated April 25, 2008, which are filed with the SEC. As of April 30, 2008, the Company s directors and executive officers beneficially owned approximately 10,334,319 shares, or 22.9 percent, of the Company s common stock.

SAFE HARBOR FOR FORWARD-LOOKING STATEMENTS

Statements in this document regarding the proposed transaction between the Company and Cornerstone; the expected timetable for completing the transaction; future financial and operating results, including targeted product milestones; benefits and synergies of the transaction; future opportunities for the combined company; strategy, future operations, financial position, future revenues and projected costs; prospects, plans and objective of management; and any other statements about the Company s or Cornerstone s management team s future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements that are not statements of historical fact (including statements containing the words believes, plans, could, anticipates, expects, estimates, plans, should, target, will, would and similar express considered to be forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by such forward-looking statements, including: the ability to consummate the transaction; the ability to successfully integrate operations and employees; the ability to realize anticipated synergies and cost savings; the ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize the Company s and Cornerstone s products, including ZYFLO CR (zileuton) extended-release tablets; the ability to transition the management teams effectively; patient, physician and third-party payor acceptance of the Company s and Cornerstone s products, including ZYFLO CR, as safe and effective therapeutic products; the ability to maintain regulatory approvals to market and sell the Company s and Cornerstone s products, including ZYFLO CR; the ability to successfully enter into additional strategic licensing, collaboration or co-promotion transactions on favorable terms, if at all; the Company s potential inability to maintain compliance with NASDAQ listing requirements; adverse side effects experienced by patients taking the Company s or Cornerstone s products; 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 Company s ability to obtain the substantial additional funding required to conduct development and commercialization activities; the Company s dependence on its strategic collaboration with MedImmune, Inc.; the ability to obtain, maintain and enforce patent and other intellectual property protection for the Company s and Cornerstone s products, discoveries and drug candidates; and the other factors described in the Company s Annual Report on Form 10-K for the year ended December 31, 2007, as amended, filed with the SEC and other filings that the Company makes with the SEC. 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, the statements in this document reflect the Company s expectations and beliefs only as of the date hereof. Subsequent events and developments may cause the Company s expectations and beliefs to change. However, while the Company may elect to update these forward-looking statements publicly at some point in the future, the Company specifically disclaims any obligation to do so, except as expressly required by law, whether as a result of new information, future events or otherwise. These forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, business development

transactions, joint ventures or investments, other than, as applicable, the proposed transaction with Cornerstone. These forward-looking statements should not be relied upon as representing the Company s views as of any date after the date of this document.

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Operator: Good afternoon everyone and welcome to Critical Therapeutics first quarter 2008 financial results conference call. There will be an opportunity for questions and comments after the prepared remarks. At that time, if you d like to ask a question, please press star, one on your telephone keypad and a confirmation tone will indicate your line is in the question queue. You may press star, two if you would like to remove your question from the queue. At this time, I would like to turn the call over to Ms. Linda Lennox, Vice President, Investor & Media Relations. Please go ahead, Ms. Lennox.

Ms. Linda Lennox: Good afternoon, everyone, and thank you for joining us today. With me are Trevor Phillips, our President and Chief Executive Officer, Tucker Kelly, our Chief Financial Officer, and Roger Heerman, our Vice President of Sales and Marketing.

Outlining the agenda, Trevor will provide a corporate update and then Tucker will review the financial results. Then we ll open up the call for questions.

Before we get started, let me remind you that some matters to be discussed on this conference call constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In particular, statements regarding:

the proposed transaction between Critical Therapeutics and Cornerstone BioPharma Holdings;

the expected timetable for completing the transaction; and

future financial and operating results, including targeted product milestones, benefits and synergies of the transaction and future opportunities for the combined company,

constitute forward-looking statements. These statements reflect management s expectations only as of the date of this call, and involve certain risks and uncertainties that might cause actual results to differ materially from those projected. For example, the following factors could cause

actual results or events to differ materially from those indicated by such forward-looking statements: the ability to consummate the transaction, the ability to successfully integrate our operations and employees and the ability to realize anticipated synergies and cost savings. Additional factors that could cause actual results or events to differ materially are reflected in the risk factors detailed in Critical Therapeutics Annual Report on Form 10-K, as amended, and other filings Critical Therapeutics makes with the Securities and Exchange Commission.

I also want to point out that Critical Therapeutics plans to file with the SEC a Registration Statement on Form S-4 and file with the SEC and mail to its stockholders a Proxy Statement/Prospectus in connection with the pending merger with Cornerstone. The Registration Statement and Proxy Statement/Prospectus will contain important information about Critical Therapeutics, Cornerstone, the transaction and related matters. Investors and security holders are urged to read the Registration Statement and Proxy Statement/Prospectus carefully when they are available.

With that let me turn the call over to Trevor for a corporate update. Trevor?

Mr. Trevor Phillips: Thank you, Linda. I would like to provide a brief corporate update on our commercial operations, as well as our preclinical and clinical pipeline.

In the months since ZYFLO CR s initial launch in September 2007, we have seen steady growth in the uptake for the product. Based upon third-party data, we estimate that in the first quarter of 2008, total prescriptions for ZYFLO CR and ZYFLO increased 54 percent over the same period in 2007 and 15 percent over the fourth quarter 2007. Since the launch of ZYFLO CR, the four-week rolling average for ZYFLO CR and ZYFLO prescriptions has increased approximately 68 percent.

In relation to our supply chain, we disclosed in our Form 10-K filed in March 2008 that we wrote off four batches of ZYFLO CR that did not meet product release specifications and were not able to be released into commercial supply. Subsequently, an additional four batches of ZYFLO CR did not meet the same specifications, could not be released as commercial product and have also been written off. In conjunction with our three manufacturing partners, we have begun an

investigation in order to determine the cause of this issue. The issue we are seeing is that tests on product indicate that the solubility profile of the tablets is higher than the maximum allowable level required for the release at six hours, which is one of three time points tested. We believe there could be a variety of reasons for this and our current investigation is designed to identify the source of the issue. We do have additional batches in process that will need to complete release testing before we can assess whether or not they can be released into commercial supply.

Meanwhile, as a protective measure, we recently reinitiated manufacturing ZYFLO, the four-times-daily immediate-release formulation of zileuton, to ensure that commercial supply of ZYFLO is available if required in the event we continue to have issues with the supply of ZYFLO CR. If the supply issues are not resolved in the near term, we expect that our existing inventory of ZYFLO CR should support our current level of sales to wholesale distributors through mid-July of this year.

Now, turning to our pipeline, we continue to advance our clinical and preclinical product candidates, but are currently very focused on preserving our cash resources as we move forward with our pending merger with Cornerstone.

The analysis of the data generated from our Phase II clinical trial of zileuton injection is ongoing. A total of 36 patients with stable chronic asthma were enrolled into this randomized, placebo-controlled trial, and we expect to report top-line data by the middle of this year. The goal of this trial is to assess safety, efficacy and then identify the optimal dose to be tested in potential Phase III clinical trials.

Again, last month we announced the results from a Phase I clinical trial to assess the safety and tolerability of an oral single dose of the R isomer of zileuton in healthy subjects. Both dose levels of R zileuton tested in the trial were well tolerated with no serious adverse events or clinical safety concerns reported. The pharmacokinetic data obtained confirmed the R(+) zileuton to be the major component in the plasma exposure profile of racemic zileuton.

Moving to our alpha-7 program, we are currently conducting GLP toxicology studies on our lead compound and, subject to having sufficient resources to do so, we would be in a position to submit an Investigational New Drug Application in 2009.

We continue in our collaboration on the development of human monoclonal antibodies to the cytokine HMGB1 with MedImmune. At this stage in the collaboration, MedImmune continues to evaluate potential product candidates, but has not yet selected a clinical candidate.

As you know, as part of our proposed merger with Cornerstone, we anticipate there will be a strategic review of the portfolios across both companies. We expect that the combined company will seek to maximize the value of any non-core programs through out-licensing, divestiture or spin-off transactions.

Finally, as we move forward, we continue to focus on conserving our cash resources and have begin to take steps to reduce our spending on both programs and personnel. We do not expect to initiate any new clinical trials with our zileuton injection and R(+) programs without first obtaining additional resources. However, we are continuing to spend money on our alpha-7 program over the next few months to continue ongoing preclinical studies that we expect will strengthen the data package and support advancement of the lead candidate toward a potential IND filing in 2009; but we have scaled back the rate of spending in order to conserve cash. In addition, we have begun to reduce our employee base. Today, we decreased our workforce by a total of six employees, or about 8 percent of our total workforce, primarily from the R&D area. We anticipate making additional headcount reductions in the coming months in our continued effort to conserve our cash position.

Now, let me turn the call over to our Chief Financial Officer, Tucker Kelly, for a financial review of the first quarter. Tucker?

Mr. Tucker Kelly: Thank you, Trevor, and good afternoon everyone.

Net product sales of ZYFLO CR and ZYFLO totaled approximately $3.3 million in the first quarter of 2008, compared with $2.9 million of net sales of ZYFLO in the first quarter of 2007, an increase of approximately 15 percent. The increase in product revenue is primarily attributable to a 43 percent increase in prescription volume, an 11 percent price increase and a $440,000 reduction in our product return reserve for ZYFLO.

Our cost of products sold was $1.8 million in the quarter, which gave us gross margins on product sales of approximately 45 percent, compared with 75 percent in the first quarter of 2007. The cost of products sold in the first quarter of 2008 included $622,000 in an inventory write-off for four batches that are part of the supply issue for ZYFLO CR that Trevor discussed earlier. In addition, the lower gross margins reflect the increased royalty burden and higher cost of manufacturing for ZYFLO CR in comparison to ZYFLO.

Overall, our operating expenses for the quarter were $14.1 million, compared with $8.7 million in the same period for 2007, an increase of approximately 62 percent.

Research and development expenses totaled $5.4 million in the quarter, compared with $2.9 million for the first quarter of last year. The increase was primarily due to higher clinical trial expenses associated with our Phase IV ZYFLO CR trial, which we discontinued in March, as well as our zileuton injection and R(+) trials, these were offset, in part, by lower expenses associated with our alpha-7 and HMGB1 preclinical programs.

Sales and marketing expenses totaled $3.9 million in the first quarter of 2008, compared with $2.0 million in the first quarter of 2007. The increase was primarily attributable to increases in salary and other costs of employees performing sales and marketing functions, as well as an increase related to promotional materials, advertising and other costs associated with ZYFLO CR that we incurred to support the co-promotion agreement with DEY as well as an increase in fees we paid to DEY under our co-promotion agreement. These increases were partially offset by a decrease related to the amortization of deferred sales and marketing expenses.

Our general and administrative expenses were $3.2 million in the first quarter of 2008, compared with $3.1 million in the first quarter of 2007.

Our net loss for the first quarter of 2008 was $10.6 million, or $0.25 per share, compared with a net loss of $4.7 million, or $0.11 per share, in the first quarter of 2007. We ended the quarter with approximately 43.5 million shares of common stock outstanding, excluding warrants and stock options.

We also ended the first quarter with $20.5 million in cash and investments and our net cash expenditures were $13.6 million for the quarter. This compares with $3.1 million in the first quarter of 2007, which was positively impacted by the $3.0 million upfront payment that we received from DEY.

This concludes our financial update. With that, I ll turn it back over to Trevor for a discussion about our proposed merger with Cornerstone.

Mr. Trevor Phillips: Thanks, Tucker.

Let me start by saying that we understand the frustration that many of you expressed following our announcement and conference call last week in which we were not able to provide more information regarding Cornerstone s business and its historical financial results. As I said at that time, we cannot provide much detail ahead of an S-4 filing and appreciate that, because Cornerstone is a private company, that detail is difficult to obtain.

Cornerstone is an entrepreneurial company that, like Critical Therapeutics, is focused in the respiratory arena. The company was founded by Craig Collard, Cornerstone s president and CEO, who has worked to build the company up to where it is today and is the company s largest stockholder. The management team at Cornerstone owns a majority of the company and it has not received any venture or similar capital investment.

Now, with respect to Cornerstone s financials, let me try to explain in more detail why we are unable to provide any additional information until the S-4 is filed. Under the terms of the merger

agreement, Cornerstone is required to have the last three years of its financial statements re-audited by a public accounting firm that, unlike its current auditor, is registered with the PCAOB, or the Public Company Accounting Oversight Board, so that Cornerstone s audited financials that will be included in the S-4 and Proxy Statement/Prospectus will meet the standards applicable to a public company filing. The re-audit process is currently underway and, in parallel, we are preparing the remainder of the S-4 so that we will be in a position to file it with the SEC after the audit work has been completed.

We understand the desire by investors to learn more about Cornerstone as soon as possible, but we believe that it was in the best interests of the company and our stockholders to get the agreement with Cornerstone signed and then work toward filing the S-4 as quickly as possible. Please also remember that the vote by Critical Therapeutics stockholders will take place only after the S-4 has been declared effective by the SEC and we have delivered the Proxy Statement/Prospectus to our stockholders; so all stockholders will have the information needed to vote on the transaction at a special meeting of stockholders. As you already know, our two largest stockholders, Healthcare Ventures and Advanced Technology Ventures, whose representatives sit on our board of directors and who together own 19 percent, approximately, of the shares outstanding, have signed stockholder agreements to vote their shares in favor of the merger.

I d like to assure you that we are doing our best to gain the most favorable outcome for our stockholders and that we believe the proposed merger is in the best interests of our stockholders over the long-term. As more information on the merger becomes available, we will do our utmost to keep you updated.

I can only ask you, our investors, for your patience and understanding while we and Cornerstone work toward completing and filing the S-4 with the SEC, whereupon our stockholders will have the information they need to help make a voting decision. We do believe this merger offers the best chance of providing value for our stockholders.

With that I ll turn back to Linda. Linda?

Ms. Linda Lennox: Thank you, Trevor. At this time we are happy to take your questions and will answer them as much as we can. However, until we file the Form S-4 and related Proxy Statement/Prospectus, we are limited as to the extent and the type of information that we can provide. Operator, can you please open the lines for questions?

Operator: Thank you.

Ladies and gentlemen, once again, if you d like to ask a question, please press star, one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, two if you would like to remove your question from the queue.

For participants using speaker equipment, please pick up the handset in order to press the star keys. One moment please, while we poll for questions.

Once again, ladies and gentlemen, if you d like to ask a question, please press star, one on your telephone keypad. There are no questions at this time. Do you have any closing comments?

Ms. Linda Lennox: Yes. I d just like to thank everyone for joining us this afternoon. We look forward to keeping you updated on our continued progress and the status of our pending merger with Cornerstone. I ll now turn it back over to the operator.

Operator: Thank you.

Ladies and gentlemen, this concludes today s teleconference. Thank you for joining us today.

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