

CRITICAL THERAPEUTICS INC

Form 425

May 02, 2008

**Filed by Critical Therapeutics, Inc.
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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 2, 2008 at which management of Critical Therapeutics, Inc. (the Company) and Cornerstone BioPharma Holdings, Inc. (Cornerstone) presented prepared remarks and answered questions regarding 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) and the proposed merger contemplated thereunder.

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 transaction. 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, should, target, will, would and similar expressions) should also be 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 and 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 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 morning, everyone, and welcome to the Critical Therapeutics Corporate Update Conference Call.

There will be an opportunity for questions and comments after the prepared remarks. If you wish to ask a question at that time, please press star, one on your telephone keypad.

At this time, I would like to turn the call over to Ms. Linda Lennox, Vice President of Investor and Media Relations. Please go ahead, Ms. Lennox.

Ms. Linda Lennox: Good morning, everyone, and thank you for joining us on such short notice to discuss this important agreement for Critical Therapeutics.

With me from Critical Therapeutics 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. We are also pleased to be joined by Craig Collard, Cornerstone's President and Chief Executive Officer.

Outlining the agenda for this morning's call, Trevor will discuss the strategic rationale of the merger with Cornerstone and Tucker will review the terms of the transaction. Craig will make some brief comments about the pending merger from Cornerstone's perspective, and then we'll be happy to answer your questions.

Before we get started, let me remind you that some matters to be discussed in 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, the expected timetable for completing the transaction, 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 that Critical Therapeutics makes with the SEC.

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 this transaction. 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, I will turn the call over to Trevor Phillips. Trevor?

Mr. Trevor Phillips: Thank you, Linda, and good morning, everybody. Our merger announcement with Cornerstone is the result of a thorough strategic business review that our management team and Board of Directors have engaged in since last fall. The definitive merger agreement with Cornerstone represents a new opportunity for Critical Therapeutics, one that we believe can create long-term value for stockholders of both companies.

I d like to spend a few minutes discussing the strategic rationale for the merger and why we believe the combination of Critical Therapeutics and Cornerstone creates an organization with significant growth potential going forward.

Together with our Board of Directors and with the assistance of our financial advisors, Lazard, we evaluated a number of other opportunities with both public and private companies as part of the process to seek to maximize shareholder value. After our extensive review, we believe that the combination of Critical Therapeutics and Cornerstone through a stock-for-stock merger will create a more diverse specialty pharmaceutical company with the potential for a larger and broader revenue stream.

Cornerstone brings a shared focus on the development and commercialization of prescription medications for respiratory disorders. As Craig will discuss, Cornerstone has two key marketed products for respiratory indications that, through line extensions and formulation changes, it has successfully expanded in the past.

Additional line extensions and formulation changes are also under development. So, in combination with ZYFLO CR and the anticipated milestones from our own development portfolio, we believe that the combined company will be better positioned to attain critical mass as a specialty pharmaceutical company.

The principal commercial assets of the combined company will comprise a number of marketed products, including Critical Therapeutics' ZYFLO CR for the prevention and chronic treatment of asthma and Cornerstone's Spectracef and the AlleRx Dose Pack family of products. Spectracef is a third-generation cephalosporin for the treatment of pathogens commonly associated with respiratory diseases and skin conditions and the AlleRx Dose Pack family of products are used for the temporary relief of symptoms associated with allergic rhinitis.

The combined company's clinical and preclinical pipeline will include a number of product candidates. We anticipate undertaking a strategic review of these assets and plan to maximize the value of any non-core programs through out-licensing, divestiture or spin-off transactions.

Now, let me introduce our Chief Financial Officer, Tucker Kelly, who will walk you through the key terms of the merger agreement. Tucker?

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

As Trevor noted, our agreement with Cornerstone is structured as a stock-for-stock merger. Under the terms of the agreement, all outstanding shares of Cornerstone's stock will be converted into shares of Critical Therapeutics stock and all outstanding Cornerstone options and warrants will be assumed by Critical.

After the consummation of the transaction, Cornerstone's stockholders will own approximately 70 percent, and Critical Therapeutics' stockholders will own approximately 30 percent of the combined company's common stock. These percentages include shares that are issuable pursuant to outstanding Cornerstone options and warrants, but they do not include any shares that are issuable pursuant to outstanding Critical Therapeutics options and warrants.

The combined entity will operate under the name Cornerstone Therapeutics Inc. and will be headquartered at Cornerstone's offices in Cary, North Carolina.

Following the closing of the transaction, Craig Collard and the Cornerstone management team will lead the combined company and Craig will tell you a bit more about himself and his team in just a moment.

The merger agreement has been approved by the Boards of Directors of both companies and it requires approval by the stockholders of Cornerstone. The holders of a majority of the

shares of Cornerstone's issued and outstanding common stock have entered into agreements to vote in favor of the merger and to refrain from selling any of the Critical Therapeutics shares that they receive in the merger for six months following the closing of the transaction.

In addition, Critical Therapeutics' stockholders are required to approve the issuance of Critical Therapeutics stock in connection with the transaction. Healthcare Ventures and Advanced Technology Ventures, who together hold approximately 19 percent of the issued and outstanding common stock of Critical, has agreed to vote their shares in favor of the merger, which is subject to customary closing conditions.

In terms of the timeline, Critical targets filing a Registration Statement on Form S-4 and a related Proxy Statement and Prospectus with the SEC as soon as practicable to solicit the approval of the stockholders for the issuance of the Critical shares in connection with the merger. The transaction is currently targeted to close in the fourth quarter of 2008.

The Form S-4 will include information about the transaction as well as the business and financial information with respect to both Critical as well as Cornerstone.

With that, let me turn the call over to Cornerstone's President and Chief Executive Officer, Craig Collard. Craig?

Mr. Craig Collard: Thank you, Tucker, and good morning.

I am pleased to have the opportunity to participate in today's conference call. Let me begin by saying that Cornerstone is delighted about our proposed merger with Critical Therapeutics and by pooling our resources, I believe we have the opportunity to capitalize on the progress and success of our products and programs and become an important respiratory-focused specialty pharmaceutical company.

Since Cornerstone is privately held, I'm sure many of you are not familiar with our company, so let me take this opportunity to provide a brief overview of who we are and what we do.

We are located next to North Carolina's Research Triangle Park and have approximately 84 employees, including a sales force of 54 representatives who market our products primarily to allergists and primary care physicians across the country. Our focus is on the development and commercialization of prescription medications in the respiratory arena.

We currently market two key respiratory products — our AlleRx Dose Pack family of products and Spectracef.

In February of 2005, we acquired AlleRx Dose Pack, a medication indicated for the temporary relief of symptoms associated with allergic rhinitis, from Adams Respiratory Therapeutics. Since the acquisition, we have launched four line extensions that comprise our AlleRx family of products.

In October of 2006, we obtained exclusive U.S. licensing rights from Meiji Seika Kaisha for a 200 mg formulation of Spectracef, a third-generation cephalosporin, indicated for the treatment of mild to moderate infections in adults and adolescents 12 years of age and older which are caused by susceptible strains causing community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis, pharyngitis/tonsillitis and uncomplicated skin and skin-structure infections.

In addition, we are developing other formulations of Spectracef with Meiji Seika for approval and marketing in the United States.

In addition, we have rights to additional products outside of respiratory that we market with our co-promotion partners.

As Tucker mentioned, following the close of the merger, I and my management team will lead the combined company, so let me tell you a little bit about each of us.

Personally, I have more than 16 years of specialty pharmaceutical experience. I founded Cornerstone in 2004 and have built the company into a growing pharmaceutical company focused on the development and commercialization of prescription medications in the respiratory arena.

George Esgro will serve as our Vice President, Sales and Marketing. George has over 20 years of pharmaceutical experience and previously worked with Roche Laboratories, Amgen and GlaxoSmithKline.

Dr. Brian Dickson will serve as our Chief Medical Officer. Brian has over 20 years background in development at major pharmaceutical and biotech companies, including Smith Kline & French Laboratories, Searle, and Warner Lambert/Park Davis.

Steve Lutz will serve as our Executive Vice President of Manufacturing and Trade. Steve has 15 years of specialty pharmaceutical experience.

Chenyqua Baldwin will serve as our Vice President and Controller and Chenyqua has more than 18 years of experience in finance, accounting and administration and previously worked with Biovail Pharmaceuticals.

Again, I want to say how excited I am about the potential of this merger with Critical Therapeutics and the future prospects of the combined company. I look forward to growing the company to maximize value for stockholders.

With that I'll turn it back to Trevor. Trevor?

Mr. Trevor Phillips: Thank you, Craig.

So, to briefly summarize, we believe that the combination of Critical Therapeutics and Cornerstone creates a respiratory-focused, specialty pharmaceutical company with a broader suite of marketed products, together with a deeper pipeline of product candidates that can either be further developed internally or provide for significant partnering opportunities. Now, we expect the combined company will have a number of important commercial and clinical events in 2008 and 2009, and we look forward to keeping you apprised on our progress towards these objectives.

Now, with that, I'll turn the call back over to 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 we can provide.

Diego, can you please open the line for questions at this time?

Operator: Thank you, Ms. Lennox.

Ladies and gentlemen, we will now be conducting a question and answer session. If you would 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, it may be necessary to pick up your handset before pressing the star keys. We will pause for a few moments while we poll for questions.

Our first question comes from Ian Sanderson with Cowen. Please state your question.

Mr. Ian Sanderson: Good morning. Thanks for taking the question. And I joined the call late, so you may have provided this. But, is there any financial information available for Cornerstone, most importantly, with the sales of the AlleRx franchise and Spectracef R?

Mr. Tucker Kelly: It's Tucker Kelly.

No, unfortunately, at this point, as we've said before, we'll be filing the S-4 and Proxy and Cornerstone, since it's privately held, doesn't have publicly available financials. So, those will be included in the S-4 at that time.

Mr. Ian Sanderson: Okay.

And then, a follow up question on just the Critical Therapeutics pipeline - will there be - will the combined entity continue with the development of the single isomer of zileuton?

Mr. Trevor Phillips: Ian, it's Trevor. Good morning.

I mean, all of the pipeline opportunities will be, you know, reviewed and evaluated. And, you know, we all view that the isomer, you know, has potential for, you know, future development in terms of extending the life or even, you know, giving better opportunities for zileuton itself.

So, it certainly will be heavily considered by the combined entity and we'll look forward to being able to update you on the decisions once that review has been completed.

Mr. Ian Sanderson: How about some of the earlier stage, the Alpha-7 programs, whatever was left at Critical that had not been out-licensed? Are those as part of your strategic review, are those off the table or are those fair game, as well?

Mr. Trevor Phillips: They are still part of the strategic review. I mean, the Alpha-7 program continues to be a phenomenally promising program, one that we think is a significant

asset, which has been sadly under-valued by many people. But, yeah, it's, you know, a major part of Critical's asset base and as part of the review, decisions will be made once we've completed that.

Mr. Ian Sanderson: Thank you.

Operator: Thank you.

Just a reminder, if you would like to ask a question, please press star, one on your telephone keypad. To remove yourself from the queue, please press star, two. Once again, to ask a question, please press star, one. We will pause for a moment to poll for questions.

Our next question comes from Jeffrey Benison with Little Gem Life Sciences. Please state your question.

Mr. Jeffrey Benison: Okay.

So, we can't we don't know anything about the revenues because that's gonna be in the document that's coming up. So, it's a black box right now. Does the company Cornerstone have cash?

Mr. Trevor Phillips: Well, again, Jeff, I think, you know, all of that information will come out in the S-4 once .

Mr. Jeffrey Benison: It's a simple question.

Mr. Trevor Phillips: Yeah, and we will be able to answer it once we've registered it in the S-4, Jeff.

Mr. Jeffrey Benison: Okay.

So, Critical Therapeutics was trading with a market cap of near \$100 million in November. The company decided not to go to presentations for investor meetings, so the and then, the CEO quits. The CFO doesn't get the 10-K done on time, so the stock goes to 60 cents.

Then, you merge with a company that has no, absolutely no records, no sales that we can figure out. We don't know what cash they have. We don't know what pipeline they have that's worth any value. But, they get 70 percent of the entity, we get 30. Have you people purposely killed the stock?

I want to know who is the owner of Cornerstone? Who owns most of those shares? Who are the VCs involved in that company?

Mr. Trevor Phillips: Well, Jeff, all of that information .

Mr. Jeffrey Benison: Who are the VCs that own Cornerstone BioPharma? I want to know if they have a relationship with the Board of Directors of Critical and there's some kind of nonsense going on where Critical was brought down so that these guys could get a good deal with their other company .

Mr. Trevor Phillips: I can .

Mr. Jeffrey Benison: It's public information.

Mr. Trevor Phillips: Jeff, Jeff, I can assure you that the things you're talking about are not relevant to this situation. They are not and there are no associated ownerships of the two entities.

Operator: Thank you, sir.

Once again, to ask a question, please press star, one. We will pause for a moment to poll for questions.

Our next question comes from Robert Hu with JM Cohen. Please state your question.

Mr. Robert Hu: Hi, thanks for taking my call.

When do you expect to file the Proxy or the S-4?

Mr. Tucker Kelly: Right now we haven't announced a timeline for that. We'll be preparing the materials and hope to do that as quickly as we can. As we said, we expect the deal to close in the fourth quarter of 2008 and we'll update you as soon as we can on the timing of the filing of the S-4.

Mr. Robert Hu: Okay.

And what is your projected burn rate from now until the transaction closes? Do you actually have enough cash to survive until the transaction closes?

Mr. Tucker Kelly: We'll be announcing our first quarter 2008 financial results next week, but we historically have not and will not provide guidance with respect to our revenue and in this case, the cash burn going forward. But, we'll certainly update you on our cash position and other financial information shortly.

Mr. Robert Hu: Okay.

And the merger agreement as it stands does not seem to contain any kind of, you know, bridging financing component. Am I understanding it correctly?

Mr. Tucker Kelly: Can you ask that again? I'm sorry. It does not contain any?

Mr. Robert Hu: Does not containing any bridging financing component.

Mr. Tucker Kelly: No, it does not. That's correct.

Mr. Robert Hu: Okay, thank you.

Ms. Linda Lennox: Are there any additional questions, Diego?

Operator: Stand by. We're polling for questions please.

Our next question comes from Dick Drury with Constitution Research. Please state your question.

Mr. Dick Drury: I guess the only question I have is what was the purpose of having a conference call.

Mr. Trevor Phillips: In what sense? What do you mean by that? The purpose of having a conference call is to inform people of what's going forward.

Mr. Dick Drury: Yeah. Well, you've succeeded in not doing that, Trevor. I again ask what was the purpose of the conference call.

Mr. Trevor Phillips: And I've just explained it to you. We've told you what's going forward, we've announced the merger, we've explained the rationale behind that merger. That was the plan of the conference call. Detailed information cannot be given out in a situation where we're filing an S-4 until the S-4 has been registered with the SEC and that's what will happen.

Operator: Thank you.

There are no further questions at this time. I will turn the conference back over to Linda Lennox for closing comments.

Ms. Linda Lennox: Well, thank you all for joining us this morning. We look forward to keeping you updated on our continued progress and the status of our pending merger with Cornerstone. This now concludes our call and you may disconnect.

Operator: Thank you.

Thank you all for joining us today. All parties may disconnect now.

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