CRITICAL THERAPEUTICS INC
Form 425
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Filed by Critical Therapeutics, Inc.
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Subject Company: Cornerstone BioPharma Holdings, Inc.
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This filing consists of the textual representation of a transcript of a webcast conference call held on August 11, 2008 at which management of Critical Therapeutics, Inc. (Critical Therapeutics) presented prepared remarks regarding Critical Therapeutics financial results for the three months ended June 30, 2008, ongoing business matters, including with respect to the supply chain for ZYFLO CR® (zileuton) extended-release tablets, and the status of the proposed transaction with Cornerstone BioPharma Holdings, Inc. (Cornerstone) pursuant to the Agreement and Plan of Merger entered into by and among Critical Therapeutics, Neptune Acquisition Corp., a wholly owned subsidiary of Critical Therapeutics, Cornerstone and Cornerstone BioPharma, Inc., a wholly owned subsidiary of Cornerstone, on May 1, 2008 (the Merger Agreement).

FORWARD-LOOKING STATEMENTS

Any statements in this filing about future expectations, plans and prospects for Critical Therapeutics, including, without limitation, statements regarding the proposed transaction with Cornerstone, including the expected timetable for completing the transaction; future financial and operating results, including the anticipated strategic review of Critical Therapeutics clinical and preclinical pipeline and subsequent actions related thereto; benefits and synergies of the transaction with Cornerstone; future opportunities for the combined company; future sales and marketing efforts for currently marketed products; possible therapeutic benefits and market acceptance of currently marketed products or product candidates; the continued availability of ZYFLO CR; the progress and timing of product development programs and related trials and regulatory submissions; strategy, future operations, financial position and future revenues or projected costs; prospects, plans and objectives of management; and all other statements that are not purely historical in nature, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Without limiting the foregoing, the words anticipate, believe, estimate, expect, int target, may, plan, project, could, should, will, would and similar expressions are intended to identify fo statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks and uncertainties relating to: the ability to consummate the proposed transaction with Cornerstone; the ability to successfully integrate operations and employees with Cornerstone; the ability to realize anticipated synergies and cost savings of the transaction with Cornerstone; the continued listing of Critical Therapeutics common stock on NASDAQ and the ability to achieve and sustain compliance with all NASDAQ listing requirements; the ability to successfully market and sell currently marketed products and product candidates, including the success of co-promotion arrangements; the ability to transition Critical Therapeutics management team effectively; the ability to develop and maintain the necessary sales, marketing, distribution and manufacturing capabilities to commercialize currently marketed products; patient, physician and third-party

payor acceptance of currently marketed products as a safe and effective therapeutic products; adverse side effects experienced by patients; the heavy dependence on the commercial success of a small number of currently marketed products; the ability to maintain regulatory approvals to market and sell currently marketed products; the ability to successfully enter into additional strategic co-promotion, collaboration or licensing transactions on favorable terms, if at all; the results of preclinical studies and clinical trials with respect to products under development and whether such results will be indicative of results obtained in later clinical trials; the ability to obtain the substantial additional funding required to conduct development and commercialization activities; the dependence by Critical Therapeutics on its strategic collaboration with MedImmune, Inc.; and the ability to obtain, maintain and enforce patent and other intellectual property protection for currently marketed products and product candidates. These and other risks are described in greater detail in the Risk Factors sections of the Registration Statement on Form S-4 filed by Critical Therapeutics with respect to the proposed transaction with Cornerstone, Critical Therapeutics Quarterly Report on Form 10-Q and other filings that Critical Therapeutics makes with the Securities and Exchange Commission (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, statements in this filing reflect the expectations and beliefs of Critical Therapeutics only as of the date hereof. Critical Therapeutics anticipates that subsequent events and developments will cause these expectations and beliefs to change. However, while Critical Therapeutics may elect to update these forward-looking statements publicly at some point in the future, it specifically disclaims any obligation to do so, except as required by law, whether as a result of new information, future events or otherwise. In general, except as specifically indicated, 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 views of Critical Therapeutics as of any date subsequent to the date hereof.

IMPORTANT ADDITIONAL INFORMATION

In connection with the proposed transaction with Cornerstone, Critical Therapeutics has filed with the SEC a Registration Statement on Form S-4 that includes a preliminary Proxy Statement/Prospectus and plans to file with the SEC and mail to its stockholders a definitive Proxy Statement/Prospectus. The Registration Statement and the preliminary Proxy Statement/Prospectus contain, and the definitive Proxy Statement/Prospectus when it becomes available will contain, important information about Critical Therapeutics, Cornerstone, the transaction and related matters. **Investors and security holders are urged to read carefully the Registration Statement and the preliminary Proxy Statement/Prospectus and, when it becomes available, the definitive Proxy Statement/Prospectus.**

Investors and security holders may obtain free copies of the Registration Statement and the preliminary Proxy Statement/Prospectus and other documents filed with the SEC by Critical Therapeutics, including the definitive Proxy Statement/Prospectus when it becomes available, 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, after it is declared effective, and the definitive Proxy Statement/Prospectus, when it becomes available, from Critical Therapeutics by contacting Critical Therapeutics, Inc., Attn: Chief Financial Officer, 60 Westview Street, Lexington, MA 02421.

Critical Therapeutics, 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 Critical Therapeutics directors and executive officers is contained in Critical Therapeutics Annual Report on Form 10-K for the year ended December 31, 2007, as amended, its Proxy Statement dated April 25, 2008 with respect to Critical Therapeutics 2008 annual meeting of stockholders, its Current Reports on Form 8-K dated April 24, 2008 and July 16, 2008 and the preliminary Proxy Statement/Prospectus with respect to the proposed transaction with Cornerstone, each of which are filed with the SEC. Additional information regarding the interests of these and other persons who may be deemed to be participants in the proposed transaction may be obtained by reading the Registration Statement, after it is declared effective, and the definitive Proxy Statement/Prospectus, when it becomes available. As of June 30, 2008, Critical Therapeutics directors and executive officers beneficially owned approximately 10,406,191 shares, or 23 percent, of Critical Therapeutics common stock.

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Operator: Good afternoon, everyone, and welcome to Critical Therapeutics second quarter 2008 financial results conference call.

There will be an opportunity for questions and comments after the prepared remarks. At that time, if you would 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.

As a reminder, this call is being recorded on Monday, August 11, 2008.

At this time, I would like to turn the call over to Ms. Linda Lennox, Vice President, Investor and 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 the call up 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 quarterly report on Form 10-Q and other filings Critical Therapeutics makes with the Securities and Exchange Commission.

On July 22nd, 2008, Critical Therapeutics filed with the SEC a Registration Statement on Form S-4 that includes a preliminary Proxy Statement and Prospectus, and plans to file with the

SEC and mail to its stockholders a definitive Proxy Statement and Prospectus in connection with the pending merger with Cornerstone.

The Registration Statement and preliminary Proxy Statement/Prospectus contain, and the definitive Proxy Statement/Prospectus will when it becomes available, will contain important information about Critical Therapeutics, Cornerstone, the transaction, and related matters.

Investors and security holders are urged to carefully read the Registration Statement and preliminary Proxy Statement/Prospectus and the definitive Proxy Statement/Prospectus when it becomes available.

The Registration Statement has not yet become effective, and the information contained therein is subject to change.

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

Mr. Trevor Phillips: Thank you, Linda.

I d like to provide a brief corporate update, as well as an update on our pending merger with Cornerstone.

On the commercial side of our business, we continue to see steady growth in the prescriptions of ZYFLO CR since its launch in September 2007. The rolling average of the four-week period ending July the 11th, 2008 compared to the four-week rolling average just prior to the launch for ZYFLO CR and ZYFLO prescriptions has increased approximately 61 percent.

Based on third-party data, total prescriptions filled in the second quarter of 2008 for ZYFLO CR and ZYFLO increased 24 percent over the first quarter of 2008, and 83 percent over the second quarter of last year.

Last quarter, we told you about a supply chain issue that we were experiencing with certain batches of ZYFLO CR and that, in conjunction with our three manufacturing partners, we

had begun an investigation to determine the cause of the issue. We had observed that solubility results for the tablets at six hours were at the high end of the range allowable for release of the product.

A consequence of this issue is that we have reserved for a total of nine batches of ZYFLO CR over the last three quarters, including one in the second quarter of 2008, that failed to meet the dissolution release criteria and could not be released into the commercial supply.

Separately, as a part of the investigation, we had placed a number of other batches of ZYFLO CR tablets with dissolution levels within the acceptable range on a quality assurance hold while we sought to identify and address the dissolution issue. Because of the ongoing investigation, we were not able to complete the manufacturing process for seven of these batches within the required timeframe. Consequently, we also recorded a reserve for these seven batches in the second quarter of 2008.

To date, the investigation has not identified a clear source for the shift in the dissolution profile. We continue to work with our manufacturing partners, and have identified a number of potential actions that we believe may help address the issue.

We did recently release one batch of ZYFLO CR, and expect to release four additional batches starting this month to wholesale distributors and retail pharmacies. Assuming the release of these five batches, and based upon our current level of product sales, we estimate that there will be sufficient inventory in the commercial supply chain to continue to provide ZYFLO CR to patients through to the end of this year.

Finally, as we mentioned in our last quarterly call in May, we did reinitiate the manufacturing of ZYFLO, the four-times-daily immediate-release formulation of zileuton, to ensure that a commercial supply of ZYFLO is available, if required, and help manage the

potential impact to patients in the event we continue to experience issues with the supply of ZYFLO CR. We currently expect to have ZYFLO available for distribution in September.

Our development pipeline includes two clinical-stage programs, zileuton injection and the R isomer of zileuton, and two preclinical programs, our proprietary alpha-7 inflammation program and our HMGB1 program, which is partnered with MedImmune.

In our continuing effort to conserve cash and reduce expenses, we do not expect to conduct any additional clinical or preclinical trials for these programs in the near future.

Following consummation of the merger with Cornerstone, we anticipate that the combined company will implement a strategic review of its product development pipeline, during which it may seek to maximize the value of any non-core programs through out-licensing, divestiture, or spin-off transactions.

Operationally, we continue to prudently manage our cash resources by reducing expenses where possible. During the second quarter, we implemented two restructurings that decreased our workforce by 21 employees, or approximately 28 percent.

Finally, let me take a minute to update you on the status of our proposed merger with Cornerstone. Since we announced the signing of the definitive agreement in May, we have been working very hard with Cornerstone to prepare and file the Registration Statement on Form S-4 and preliminary Proxy Statement/Prospectus, which I am pleased to report we filed with the SEC on July the 22nd.

With this filing, investors now have access to a significant amount of detailed information about Cornerstone s business and the proposed transaction. I believe that stockholders who have had a chance to review the S-4 can now better understand the potential benefits of the opportunity with Cornerstone.

As Linda mentioned earlier, the Registration Statement has not yet become effective, and the information contained therein is subject to change.

As was expected, the SEC recently informed us that they will be conducting a full review of the filing. Once we receive the SEC s comments, we plan to work quickly to address their questions so we can fix the date for the special meeting of stockholders, mail the proxy statement, and complete the transaction following stockholder approval. Based on the current timeline, we expect that the transaction will close during the fourth quarter of 2008.

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

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

Net product sales of ZYFLO CR and ZYFLO totaled approximately $3.9 million in the second quarter of 2008, compared with $2.3 million of net sales of ZYFLO in the second quarter of 2007, an increase of approximately 70 percent. The increase in product revenue is primarily attributable to an 83 percent increase in prescription volume and an 11 percent price increase.

Our cost of product sold was $2.8 million in the second quarter, compared with $680,000 in the second quarter of last year. Gross margins on product sales decreased to 27 percent from 70 percent in the second quarter of 2007. This significant decrease was primarily due to a charge of $1.3 million related to eight batches of ZYFLO CR that either could not be released in the commercial supply chain or could not complete the manufacturing process in the required timeframe as a result of the supply chain issues with ZYFLO CR that Trevor mentioned earlier in the call.

In addition, the lower gross margins in the second quarter of this year reflect the increased royalty burden and higher cost of manufacturing for ZYFLO CR in comparison to ZYFLO.

Overall, our operating expenses totaled $10.5 million in the second quarter, a 38 percent decrease from the second quarter of 2007.

Research and development expenses decreased 85 percent to $1.6 million, down from 10.1 million in the second quarter of last year. The decrease is primarily due to milestone fees that were paid and accrued for in the second quarter of 2007, following the FDA s approval of ZYFLO CR.

In addition, we had lower clinical and preclinical expenses associated with our ZYFLO CR Phase IV trial, which was discontinued in March 2008, and our alpha-7 and HMGB1 programs.

Sales and marketing expenses decreased 17 percent to 2.2 million, compared with 2.6 million in the second quarter of 2007.

General and administrative expenses decreased 21 percent to 2.8 million in the second quarter of this year, compared with 3.5 million in the second quarter of last year.

Additionally, our operating expenses in the second quarter included a charge of approximately $1.2 million related to the two restructurings we implemented in May and June 2008 related to the termination of 21 employees.

Our net loss in the second quarter of 2008 was 6.6 million, or 15 cents per share, compared to the net loss of $13 million, or 30 cents per share, in the second quarter of 2007.

We ended the quarter with approximately 43 million shares of common stock outstanding, excluding warrants and stock options.

As of June 30th, 2008, our cash and investments totaled $11.2 million after net cash expenditures of $9.3 million during the second quarter. This compares with net cash expenditures of 5.5 million in the second quarter of 2007, which was positively impacted by a $4 million milestone payment that we received from DEY upon the FDA s approval of ZYFLO CR in May 2007.

This concludes our financial update. With that, I ll turn it back over to Trevor for some concluding remarks.

Mr. Trevor Phillips: Thank you, Tucker.

Before we take questions, I wanted to conclude the prepared remarks by again outlining why we believe the proposed transaction with Cornerstone is in the best interests of Critical Therapeutics stockholders.

The merger with Cornerstone would create a larger respiratory-focused specialty pharmaceutical company with multiple marketed products, a more balanced revenue stream, and important product development opportunities.

The combined company will be able to focus its resources on developing a successful specialty pharma business without the additional challenge of trying to build an early-stage drug development pipeline in parallel.

In addition, there are significant potential synergies that we believe can be achieved by consolidating the infrastructures of the two companies and allowing management to fully leverage its sales force across multiple revenue-generating products.

We believe that the merger with Cornerstone offers the best opportunity for future growth for our stockholders, and look forward to seeking your approval for the deal in the coming months.

Now with that, I d like to turn the call back to Linda.

Ms. Linda Lennox: Thank you, Trevor.

As this time, we d be happy to take your questions. Operator, please open the line for questions.

Operator: Thank you.

Ladies and gentlemen, we will now be conducting a question and answer session. Again, 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.

Once again, that s star followed by one on your telephone keypad for questions. One moment, please, while we poll for questions.

As a reminder, if you d like to ask a question, please press star followed by one on your telephone keypad.

Ms. Linda Lennox: Are there any questions, Joe?

Operator: I m showing no questions in the queue.

Ms. Linda Lennox: Okay.

Well, thank you all 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.
That concludes our conference call. Thank you for joining us today. You may disconnect your lines at this time.
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