CERUS CORP
Form 8-K
March 27, 2006

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 24, 2006

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**0-21937**	**68-0262011**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2411 Stanwell Drive

Concord, California 94520

(Address of principal executive offices) (Zip Code)

Registrant s telephone number, including area code: (925) 288-6000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On March 24, 2006, Cerus Corporation (the Company) met with the FDA to discuss the Company s Phase III development plan for the INTERCEPT Blood System for platelets. As a result of this meeting, the Company continues to expect that the FDA will require an additional Phase III clinical trial to evaluate the hemostatic efficacy and safety of the platelet system, using the Company s final commercial product design, as compared to conventional platelets. Based on the meeting with the agency, the Company understands that its reassessment of its previously completed Phase III clinical trial data will not be sufficient to address the apparent differences observed in that trial between the treatment groups in the category of pulmonary adverse events, and that data on such events would need to be gathered in the additional Phase III trial. The additional clinical trial would need to be completed and data from the trial submitted to the FDA before the Company could complete a pre-market approval application to the FDA. Before the Company can begin an additional clinical trial, the Company will need to gain concurrence with the FDA on the Company s trial design.

This Current Report on Form 8-K contains forward-looking statements. For this purpose, any statements contained in this report that are not statements of historical fact may be deemed forward-looking statements, including, without limitation, statements regarding the Company s potential additional Phase III clinical trial of the INTERCEPT Blood System for platelets. Words such as expect, would, will and similar words or expressions or the negative of these words or expressions are intended to identify forward-looking statements. Actual results could differ materially from these forward-looking statements as a result of certain factors, including, without limitation, risks related to (i) the Company s ability to reach concurrence with the FDA on the size, scope or design of the potential additional Phase III clinical trial in a timely manner, or at all, and the fact that failure to do so would delay or prevent clinical development and potential commercialization of the INTERCEPT Blood System for platelets in the U.S.; (ii) whether the FDA would find the results of any additional clinical trials to be acceptable for approval and (iii) other risks detailed in the Company s filings with the Securities and Exchange Commission, including the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2005. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. The company does not undertake any obligation to update any forward-looking statements as a result of new information, future events, changed assumptions or otherwise.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CERUS CORPORATION

Dated: March 27, 2006

By: /s/ Howard G. Ervin
Howard G. Ervin
Vice President, Legal Affairs