CERUS CORP

FORM 8-K
(Current report filing)

Filed 11/17/09 for the Period Ending 11/16/09

Address	2550 STANWELL DRIVE CONCORD, CA 94520
Telephone	9252886000
CIK	0001020214
Symbol	CERS
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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): 11/16/2009

Cerus Corporation
(Exact name of registrant as specified in its charter)

Commission File Number: 0-21937

Delaware	**68-0262011**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**

2411 Stanwell Drive
Concord, California 94520
(Address of principal executive offices, including zip code)

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

(Former name or former address, if changed since last report)

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:

[ ] 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 November 16, 2009 Cerus Corporation (the "Company") announced the results of its meeting with the U.S. Food and Drug Adminstration's Blood Products Advisory Committee (BPAC) related to the design for a potential U.S. Phase III clinical trial of the INTERCEPT Blood System for platelets.

A copy of the Company's press release, entitled "Cerus Corporation Receives FDA Blood Products Advisory Committee Guidance for Proposed INTERCEPT Blood System Phase III Trial Design," is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

99.1 Press Release, dated November 16, 2009, entitled "Cerus Corporation Receives FDA Blood Products Advisory Committee Guidance for Proposed INTERCEPT Blood System Phase III Trial Design."

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

Date: November 17, 2009

By: /s/ Howard G. Ervin

Howard G. Ervin
Vice President, Legal Affairs

EXHIBIT INDEX

Exhibit No.	Description
EX-99.1	Press Release, dated November 16, 2009, entitled "Cerus Corporation Receives FDA Blood Products Advisory Committee Guidance for Proposed INTERCEPT Blood System Phase III Trial Design."

Cerus Corporation Receives FDA Blood Products Advisory Committee Guidance for Proposed INTERCEPT Blood System Phase III Trial Design

CONCORD, Calif.--(BUSINESS WIRE)--Nov 16, 2009-- Cerus Corporation (NASDAQ:CERS) announced today that the FDA's Blood Products Advisory Committee (BPAC) rendered a positive opinion on the proposed hemostatic efficacy and safety endpoints for a potential U.S. Phase III clinical trial of the INTERCEPT Blood System for platelets. The Committee disagreed with the safety margins for the trial proposed by Cerus, and recommended that the trial design include more stringent safety margins for comparing INTERCEPT-treated platelets and conventional platelets. In addition, the Committee rendered a positive opinion on a proposed pathway forward in which successful completion of the proposed Phase III trial would be followed by a post-marketing randomized control study and concurrent staged roll-out of the product.

"The Committee's guidance supports further development of INTERCEPT in the United States," said Claes Glassell, president and chief executive officer of Cerus. "We now need to conduct further discussions with the FDA to agree upon a final protocol. The more stringent safety margins recommended by the Committee may require a clinical trial with a larger number of patients than had been proposed. We expect that it will take at least 12 months to complete the clinical trial preparations and partnering arrangements necessary for commencement of the potential trial."

The proposed Phase III clinical trial is designed as a randomized, double-blinded, non-inferiority trial to assess the hemostatic efficacy and safety of routine use of INTERCEPT-treated platelets compared to platelets prepared with conventional processes. The proposed primary efficacy endpoint is number of days of Grade 2 bleeding (World Health Organization scale), and the proposed primary safety endpoint is the incidence of acute lung injury (ALI).

Previously, Cerus completed a U.S. Phase III trial for INTERCEPT-treated platelets, the SPRINT trial, which enrolled 645 patients. The SPRINT trial met its primary endpoint of the proportion of patients with Grade 2 bleeding, indicating non-inferiority of INTERCEPT platelets compared to conventional platelets. While acknowledging this outcome, the FDA expressed concerns regarding observed differences between the test and control arms of the study and had indicated that it needed more data to support a pre-market approval application. The new Phase III trial will be designed to resolve the FDA's questions regarding hemostatic efficacy and safety.

The FDA seeks the advice of an advisory committee such as the BPAC when evaluating a potential new product. A final decision is made by the FDA and while the FDA is not required to follow the advice of its advisory committee, it often does.

ABOUT THE INTERCEPT PLATELET SYSTEM
The INTERCEPT Blood System for platelets is designed to reduce the risk of transfusion-transmitted diseases by inactivating a broad range of pathogens such as viruses, bacteria and parasites that may be present in donated blood. The nucleic acid targeted mechanism of action allows INTERCEPT treatment to inactivate both historical transfusion threats, such as hepatitis,

HIV and bacteria, as well as emerging pathogens such as influenza, West Nile virus, malaria and dengue. The platelet system was granted CE mark registration in 2002, and subsequently received additional European regulatory approvals in France (Afssaps), Switzerland (Swissmedic), and Germany (Paul Ehrlich Institute marketing authorization for the German Red Cross). Over 300,000 units of INTERCEPT platelets have been successfully transfused to date.

ABOUT CERUS

Cerus Corporation is a biomedical products company focused on commercializing the INTERCEPT Blood System to enhance blood safety. Cerus currently markets and sells the INTERCEPT Blood System for both platelets and plasma in Europe, Russia, the Middle East and selected countries in other regions around the world. The INTERCEPT red blood cell system is in clinical development. See http://www.cerus.com for more information.

This press release contains forward-looking statements. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements, including, without limitation, statements relating to potential FDA agreement on the trial design for, and the potential commencement of, a U.S. Phase III clinical trial of INTERCEPT platelets, Cerus' expectations regarding the length of time required to complete potential partnering arrangements and other actions necessary for the commencement of the potential U.S. Phase III clinical trial, other potential development and U.S. regulatory actions or events related to INTERCEPT platelets, including continued development of INTERCEPT platelets in the U.S., and Cerus' ability to resolve the FDA's concerns regarding safety and efficacy. Actual results could differ materially from these forward-looking statements as a result of certain factors, including, without limitation, risks associated with BPAC recommendations relating to the proposed trial design and overall proposed regulatory pathway, FDA's lack of obligation to follow BPAC recommendations, Cerus' ability to reach agreement with the FDA on the proposed trial design, Cerus' need for additional funding from partners or other sources in order to conduct the potential Phase III clinical trial and its ability to obtain that funding or to complete any partnering arrangements or both, the absence of which would preclude any commencement of the potential Phase III clinical trial, whether the number of patients required to be enrolled in the potential Phase III clinical trial or in any post-marketing study would be prohibitively large due either to cost, logistics or both, Cerus' ability to enroll an adequate number of patients in the potential Phase III clinical trial in a timely manner or at all, whether data collected in such a trial will be adequate to address FDA concerns regarding the safety and efficacy of INTERCEPT platelets, and risks associated with conducting clinical trials, including the risk of failure, delays and required changes in the clinical trial design even if original objectives are being met, as well as other risks detailed in the Cerus' filings with, the Securities and Exchange Commission (SEC), including in Cerus' quarterly report on Form 10-Q for the quarter ended September 30, 2009, filed with the SEC on November 6, 2009. No pathogen inactivation system has been shown to inactivate all pathogens. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Cerus does not undertake any obligation to update any forward-looking statements as a result of new information, future events, changed assumptions or otherwise.

Contacts:

Lainie Corten

Director, Global Communications & Marketing

Cerus Corporation

(925) 288-6319

Jason Spark

Porter Novelli Life Sciences

(619) 849-6005