CERUS CORP

FORM 8-K
(Current report filing)

Filed 08/22/00 for the Period Ending 08/22/00

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

CERUS CORP

FORM 8-K
(Unscheduled Material Events)

Filed 8/22/2000 For Period Ending 8/22/2000

Address	2411 STANWELL DR
	CONCORD, California 94520
Telephone	925-288-6000
CIK	0001020214
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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): August 22, 2000

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of incorporation)

0-21937	68-0262011
(Commission File No.)	(IRS Employer Identification No.)

2525 STANWELL DR., SUITE 300
CONCORD, CALIFORNIA 94520

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (925) 603-9071

ITEM 5. OTHER EVENTS.

On August 22, 2000, Cerus Corporation, with its development partner, Baxter Healthcare Corporation, announced the results of their European Phase 3 clinical trial of the Intercept(TM) system to inactivate pathogens in platelets. The press release announcing the results of the trial is filed as Exhibit 99.1 hereto. The data and results from the trial are filed as Exhibit 99.2 hereto.

ITEM 7. EXHIBITS.

99.1	Press Release, dated as of August 22, 2000 entitled "Cerus and Baxter Announce Results of European Phase 3 Trial of Their Intercept Platelet System for Pathogen Inactivation"
99.2	Data and Results from European Phase 3 Trial of the Intercept Platelet System for Pathogen Inactivation

SIGNATURE

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, thereunto duly authorized.

CERUS CORPORATION

Dated: August 22, 2000

By: /s/ GREGORY W. SCHAFER

Gregory W. Schafer
Chief Financial Officer

INDEX TO EXHIBITS

99.1	Press Release, dated as of August 22, 2000 entitled "Cerus and Baxter Announce Results of European Phase 3 Trial of Their Intercept Platelet System for Pathogen Inactivation"
99.2	Data and Results from European Phase 3 Trial of the Intercept Platelet System for Pathogen Inactivation

EXHIBIT 99.1

Contacts:

Greg W. Schafer	Margaret Shubny	Bethanee Martin
Cerus Corporation	Baxter Healthcare Corp.	Edelman Public Relations Worldwide
(925) 603-9071	(847) 948-3951	(415) 486-3235
ir@cerus.com	stanfom@baxter.com	bethanee.martin@edelman.com

CERUS AND BAXTER ANNOUNCE RESULTS OF EUROPEAN PHASE 3 TRIAL OF THEIR INTERCEPT PLATELET SYSTEM FOR PATHOGEN INACTIVATION

DATA SUPPORTS SUBMISSION FOR EUROPEAN REGULATORY APPROVAL

CONCORD, CALIF. AND DEERFIELD, ILL., AUGUST 22, 2000 - Cerus Corporation (NASDAQ: CERS), a pioneer in systems to enhance the safety of the blood supply, and its development partner, Baxter Healthcare Corporation, announced today that the results of their European Phase 3 clinical trial of the Intercept Platelet System support a planned submission for regulatory approval to market the system in Europe. The companies are developing Intercept Blood Systems to protect against the transmission of infectious diseases through blood transfusions. The Intercept Platelet System is the only pathogen inactivation system for platelets to enter human clinical trials.

The 103 patient study was designed to assess the therapeutic efficacy and safety of platelets treated with the Intercept Platelet System. Patients also were monitored for bleeding, acute transfusion reactions and other adverse events. The purpose of the study was to determine whether platelets treated with the Intercept Platelet System provide platelet transfusion support consistent with current medical practice. The study included platelet-deficient cancer patients in four academic medical centers in the United Kingdom, France, the Netherlands and Sweden.

"This study shows that physicians can provide their patients the added security of pathogen-inactivated platelets while delivering the therapeutic benefits required of platelet transfusions," said Dr. D. van Rhenen of Bloodbank Rotterdam, the Netherlands, the lead investigator on the study.

The trial had two primary endpoints: corrected count increment and platelet count increment, each one-hour after transfusion. The corrected count increment measures the increase in the patient's platelet count after a platelet transfusion, corrected for transfusion platelet dose and the patient's blood volume. For this measure, one-hour after transfusion, the performance of treated platelets was similar to that of the untreated platelets.

The platelet count increment, which measures the platelet count increase without correcting for dosage or blood volume, is influenced by the platelet dose the patient receives. In this study the platelet dose per transfusion of treated platelets was approximately ten percent lower than that of untreated platelets. The resulting platelet count increment one-hour after transfusion of treated platelets was statistically lower than that after transfusion of untreated platelets. However, both the platelet dose per transfusion and the platelet count increment one hour after transfusion were within the typical therapeutic range reported in medical literature for untreated platelets.

Secondary endpoints for the study included multiple factors relevant to clinical efficacy and safety. The results for two important indicators of clinical efficacy, the number of patients with a major bleeding episode and the number of red blood cell transfusions, were comparable for the treated and untreated platelets. Similarly, the time between platelet transfusions, the total platelet dose per patient and the number of adverse events were similar between the two groups. Both the platelet count increment and the corrected count increment measured 24 hours after transfusion, while statistically lower than those following the transfusion of untreated platelets, were within the typical therapeutic range reported in medical literature for untreated platelets.

"This is a pivotal step in our mission to enhance the safety of the blood supply," said Stephen Isaacs, Cerus president and chief executive officer. "The Intercept Platelet System is paving the way in our comprehensive approach to the inactivation of pathogens in all three transfusion blood components."

"We are pleased with the results of this study. Baxter and Cerus expect to be the first to file for regulatory approval of a pathogen inactivation system for platelets," stated Harry M. Jansen Kraemer, Jr. Baxter chairman and chief executive officer. "This is a significant step forward in our pathogen inactivation programs."

Intercept Blood Systems are designed to inactivate viruses, bacteria and other pathogens, as well as white blood cells, which have been associated with a variety of transfusion reactions. Intercept Blood Systems are based on Cerus' proprietary Helinx technology, which has been developed to inactivate blood-borne pathogens while leaving the therapeutic properties of the blood component intact. Previous studies have demonstrated the ability of the Helinx technology to inactivate a broad array of pathogens that may be present in blood products.

The companies are conducting a 600 patient Phase 3 clinical trial of the Intercept Platelet System in the United States. A Phase 3 clinical trial of the Intercept Plasma System and Phase 1 clinical trials of the Intercept Red Blood Cell System are also underway in the United States.

Cerus and Baxter are submitting the results of the European Phase 3 clinical trial for presentation at the annual meeting of the American Society of Hematology in December 2000.

ABOUT CERUS

Cerus Corporation is developing systems to enhance the safety of the world's blood supply. These systems are based on Cerus' Helinx technology, which has the ability to prevent the replication of viruses, bacteria and other pathogens and to control cellular proliferation. The Concord, Calif.-based biopharmaceutical company is currently conducting the first human

clinical trials of pathogen-inactivated platelets, as well as clinical trials of fresh frozen plasma (FFP) and red blood cells, in collaboration with Baxter Healthcare Corporation.

ABOUT BAXTER

Baxter Healthcare is the principal domestic operating subsidiary of Baxter International (NYSE: BAX). Baxter International, through its subsidiaries, is a global medical products and services company that provides critical therapies for people with life-threatening conditions. The company's products and services in bioscience (biopharmaceuticals and blood collection, separation and storage devices), medication delivery and renal therapy are used by health-care providers and their patients in more than 100 countries.

Statements in this news release regarding product development, clinical development and regulatory activity are forward-looking statements that involve risks and uncertainties. Actual results could differ materially from the above forward-looking statements as a result of certain factors, including the uncertainty of the timing and results of any clinical trials, action by regulatory authorities, the lack of assurance of product approval, the uncertainty of market acceptance of any products, competitive conditions, the uncertainty of future financing and other factors discussed in the companies' 1999 Annual Reports on Form 10-K. More detailed information on the results of the European Phase 3 Trial are contained in a report on Form 8-K, being filed with the Securities and Exchange Commission by Cerus concurrently with this news release.

###

For more information about Cerus, call (925) 603-9071.

EXHIBIT 99.2

DATA AND RESULTS FROM EUROPEAN PHASE 3 TRIAL OF THE INTERCEPT PLATELET SYSTEM FOR PATHOGEN INACTIVATION

S-59 (HELINX TM) PHOTOCHEMICALLY TREATED (PCT) PLATELETS FOR SUPPORT OF THROMBOCYTOPENIA: RESULTS OF THE EUROSPRITE PHASE 3 TRIAL.

Photochemical treatment of platelet (plt) concentrates (PC) with the psoralen S-59 and UVA light has been shown to inactivate high titers of viruses, bacteria and leukocytes. A randomized, double blind intent-to-treat trial was conducted at 4 European sites to compare the efficacy and safety of non-(gamma)-irradiated PCT buffy coat (BC) PC and untreated PC (U-PC) (gamma)-irradiated as required (56%). 103 thrombocytopenic patients (pts) with a spectrum of malignancies were transfused with PCT-PC (n=52) or U-PC (n=51), for up to 56 days with 28 days of follow-up for adverse events. Plt tx were ordered by primary care physicians blinded to treatment assignment. Mean +/- SD, p values and 95% confidence intervals of mean differences for relevant parameters are listed below. For the purpose of the study, a statistically significant difference is defined as a p value of less then 0.05.

PARAMETER	PCT PC	UNTREATED PC	p(95% CONFIDENCE INTERVAL)
N(degree)plt transfusions (tx) per pt	7.5 +/- 5.8	5.6 +/- 5.5	0.07
Plt dose per tx (x 10 11)	3.9 +/- 1.0	4.3 +/- 1.2	<0.001
Total plt dose per pt (x 10 11)	22.3 +/- 14.5	21.2 +/- 19.4	0.68
Plt storage time (days)	3.5 +/- 1. 1	3.4 +/- 1.2	0.28
1 hr plt increment, CI (x 10 9/L)	27.6 +/- 13.3	35.8 +/- 23.2	0.02 (1.1, 15.3)
1 hr corrected CI, CCI (x 10 3)	13.1 +/- 5.3	14.8 +/- 6.2	0.16 (-0.6, 3.9)
24 hr CI (x 10 9/L)	16.0 +/- 9.8	24.7 +/- 17.4	0.002 (3.3, 14.0)
24 hr CCI (x 10 3)	7.3 +/- 5.4	10.6 +/- 7.1	0.01 (0.8, 5.7)
Plt tx interval (days)	3.0 +/- 1.2	3.4 +/- 1.2	0.10
N(degree)pts refractory to plt tx	4/52 (8%)	3/51 (6%)	0.73
N(degree)tx with acute tx reactions	21/390 (5%)	13/287 (5%)	0.61
N(degree)pts with acute tx reactions	15/52 (29%)	8/51 (16%)	0.11
N(degree)RBC tx	4.9 +/- 4.2	4.5 +/- 5.4	0.63
N(degree)pts with major hemorrhage	5 /52 (10%)	4/51 (8%)	0.77

Hemostasis after both types of transfusions was comparable. PCT-PC provided plt CI, CCI and tx intervals within the typical therapeutic range reported in the medical literature. Bleeding, RBC tx, acute tx reactions, and refractoriness to

plt tx were similar between groups.