CERUS CORP

FORM 8-K
(Current report filing)

Filed 08/17/01 for the Period Ending 08/17/01

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 8/17/2001 For Period Ending 8/17/2001

Address	2411 STANWELL DR
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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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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 17, 2001

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

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

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

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

Item 5. Other Events

On August 17, 2001, Cerus Corporation, with its development partner, Baxter Healthcare Corporation, announced the results of Phase III clinical trials of the Intercept Plasma System and Intercept Platelet System. The press releases announcing the results of these clinical trials are filed herewith as Exhibits 99.1 and 99.2, respectively. The data and results from the plasma and platelet trials are filed as Exhibits 99.3 and 99.4, respectively.

Item 7. Exhibits

Exhibit 99.1	Press Release, dated August 17, 2001, entitled "Cerus and Baxter Report Primary Endpoint Met in U.S. Phase III Trial of the Intercept Plasma System".
Exhibit 99.2	Press Release, dated August 17, 2001, entitled "Cerus and Baxter Report Positive Phase III Results for the Intercept Platelet System".
Exhibit 99.3	Data and Results from the Phase III Intercept Plasma System Clinical Trial.
Exhibit 99.4	Data and Results from the U.S. Phase III Intercept Platelet System Clinical Trial.

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 hereunto duly authorized.

CERUS CORPORATION

Dated: August 17, 2001

By: /s/ GREGORY W. SCHAFER

Gregory W. Schafer
Vice President, Finance and Chief Financial Officer

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EXHIBIT 99.1

EXHIBIT 99.1

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CERUS AND BAXTER REPORT PRIMARY ENDPOINT MET IN U.S. PHASE III TRIAL OF THE INTERCEPT PLASMA SYSTEM
- Data Support Submission for U.S. Regulatory Approval -

CONCORD, Calif., and DEERFIELD, Ill., August 17, 2001—Cerus Corporation (Nasdaq: CERS) and Baxter Healthcare Corporation today reported that the INTERCEPT Plasma System successfully met the primary endpoint of their U.S. Phase IIIb clinical trial. These data further support the safety and therapeutic effectiveness of plasma treated with the INTERCEPT Plasma System, which is being developed to protect against transmission of infectious diseases that may result from plasma transfusions.

"These results are significant because they demonstrate that we can offer the pathogen inactivation process with the INTERCEPT Plasma System while maintaining therapeutic performance," said Stephen T. Isaacs, president and chief executive officer of Cerus. "These results will be added to our arsenal of data supporting the safety and efficacy of the INTERCEPT Plasma System, including preclinical studies demonstrating inactivation of a broad spectrum of blood borne pathogens."

The multicenter randomized, controlled, double blind Phase IIIb trial included 121 patients with acquired defects in coagulation, primarily due to end-stage liver disease. These patients generally require plasma support during surgery or other invasive procedures, including liver transplantation. The trial evaluated the blood clotting function of INTERCEPT plasma compared to untreated plasma to determine whether the pathogen inactivation treatment process affected therapeutic performance. Blood clotting function was measured using prothrombin (PT) and partial thromboplastin (PTT) times, widely used measures of blood clotting function. The primary endpoint of the trial was a comparison of PT and PTT responses between INTERCEPT plasma and untreated plasma during a seven-day treatment period. The results, which achieved the trial's statistical threshold, showed that the ability of INTERCEPT plasma to treat bleeding was statistically comparable to that of untreated plasma. In addition, the safety profile of INTERCEPT plasma was comparable to untreated plasma. Data measuring secondary endpoints, examined in later transfusions, are still being analyzed. The companies will submit data from this study for presentation at a forthcoming scientific meeting.

Approximately seven million plasma transfusions are performed annually in Western Europe, North America and Japan to overcome blood-clotting deficiencies and to facilitate healing. While donated plasma is generally tested for a limited number of specific pathogens, testing does not eliminate the risk of viral contamination. The INTERCEPT Plasma System is being developed to enhance the safety of plasma transfusions by targeting the nucleic acid of a broad spectrum of viruses, bacteria, other pathogens and white blood cells. The companies are currently conducting a 30-patient Phase IIIc trial to evaluate INTERCEPT plasma to treat thrombotic thrombocytopenic purpura, a sporadic disease that requires repeated total blood volume plasma exchange to achieve remission.

Cerus and Baxter are collaborating on the development of the INTERCEPT Blood Systems to enhance the safety of blood transfusions. In a separate release today, the companies announced that the primary endpoint had been met in the U.S. Phase III clinical trial of the INTERCEPT Platelet System. The companies also are preparing to begin a Phase III trial for the INTERCEPT Red Blood Cell System.

ABOUT CERUS

Cerus Corporation is developing medical systems and therapeutics based on its proprietary Helinx™ technology for controlling biological replication. Cerus' most advanced programs are focused on systems to enhance the safety of the blood products used for transfusion. These INTERCEPT Blood Systems, based on the company's Helinx technology, are designed to inactivate viruses, bacteria, other pathogens and white blood cells. The Concord, California-based company also is pursuing therapeutic applications of Helinx technology to treat and prevent serious diseases.

ABOUT BAXTER

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

Statements in this news release regarding product development and product potential 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 risks and uncertainty of the timing and results of clinical trials and other development activities, actions by regulatory authorities at any stage of the development process, additional financing activities, market acceptance of any products, competitive conditions and other factors discussed in the companies' most recent reports on Forms 10K, 10Q and other filings with the Securities and Exchange Commission. More detailed information on the results of the Phase IIIb INTERCEPT Plasma System 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.

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EXHIBIT 99.2

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CERUS AND BAXTER REPORT POSITIVE PHASE III RESULTS FOR THE INTERCEPT PLATELET SYSTEM
- Data Support Therapeutic Effectiveness of INTERCEPT Platelets -

CONCORD, Calif., and DEERFIELD, Ill., August 17, 2001—Cerus Corporation (Nasdaq: CERS) and Baxter Healthcare Corporation today reported that the primary endpoint has been successfully met in their U.S. Phase III trial of the INTERCEPT Platelet System. The results support the effectiveness of INTERCEPT platelets to treat and prevent bleeding during severe thrombocytopenia, a medical condition characterized by a persistent reduction in platelet levels. The companies are jointly developing the INTERCEPT Platelet System, a pathogen inactivation system being developed to protect against transmission of infectious disease and occurrence of transfusion reactions, which may result from blood transfusions.

"We are very excited about these results which were collected from a broad and thorough clinical experience," said Stephen T. Isaacs, president and chief executive officer of Cerus. "These data show that our INTERCEPT Platelet System maintains the therapeutic performance of platelets which have undergone pathogen inactivation using our proprietary technology. We look forward to completing our modular PMA submission to the FDA seeking U.S. marketing approval of the product."

The randomized, controlled, double blind 671-patient clinical trial was designed to evaluate the therapeutic efficacy and safety of INTERCEPT platelets. In the trial, platelet transfusions were administered to reduce the risk of bleeding during severe thrombocytopenia and to treat active bleeding. The primary endpoint of the study was a comparison of the proportion of patients with moderate bleeding (Grade 2 World Health Organization criteria) following platelet transfusion with either INTERCEPT platelets or platelets that had not been treated with a pathogen inactivation process. The data showed that the proportion of patients with moderate bleeding between the patients who received INTERCEPT platelets and control groups was statistically equivalent and within 1% of each other, solidly achieving the trial's goal of a less than 12.5% difference between the two groups.

The study also evaluated a number of secondary endpoints comparing INTERCEPT platelets to untreated platelets, including those intended to detect differences in numbers of platelets transfused and increases in platelet counts post-transfusion. These data, some of which showed statistically significant differences, will provide physicians with additional information on INTERCEPT platelets. Data on secondary endpoints are undergoing further analysis. The companies will submit the data from this study for presentation at a forthcoming scientific meeting.

More than four million platelet transfusions are performed annually in Western Europe, North America and Japan to prevent bleeding in a variety of patients, including those undergoing cancer therapy and surgical procedures. While donated platelets are generally tested for a limited number of specific pathogens, testing does not eliminate the risk of viral contamination, and there are no routine tests to screen for bacteria. Bacterial contamination in collected platelets is of particular concern as bacteria quickly multiply in nutrient-rich platelet concentrates, which are stored at room temperature. Also, white blood cells in platelet transfusions can potentially result in graft-vs-host disease and other severe immune reactions in the transfusion recipient. The INTERCEPT Platelet System is being developed to target the nucleic acid of viruses, bacteria, other pathogens and white blood cells to improve the safety of platelet transfusions.

In a separate release today, the companies announced results from the Phase IIIb trial of the INTERCEPT Plasma System, which demonstrated that the primary endpoint of that study also was successfully met. Cerus and Baxter also are conducting a Phase IIIc trial for the INTERCEPT Plasma System and are preparing to begin a Phase III trial with their INTERCEPT Red Blood Cell System.

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Statements in this news release regarding product development and product potential 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 risks and uncertainty of the timing and results of clinical trials and other development activities, actions by regulatory authorities at any stage of the development process, additional financing activities, market acceptance of any products, competitive conditions and other factors discussed in the companies' most recent reports on Forms 10K, 10Q and other filings with the Securities and Exchange Commission. More detailed information on the results of the Phase III trial of the INTERCEPT Platelet System are contained in a report on Form 8-K, being filed with the Securities and Exchange Commission by Cerus concurrently with this news release.

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Pathogen Inactivated Fresh Frozen Plasma Prepared Using Helinx™ Technology is Efficacious and Well Tolerated in the Treatment of End-Stage Liver Disease Patients—The STEP AC Trial.

Introduction: Pathogen inactivated FFP (INTERCEPT Plasma) is prepared using amotosalen HCl (S-59) and UVA light to inactivate a broad spectrum of blood borne pathogens in single units of FFP. S-59 Treated FFP was Evaluated in Patients with Acquired Coagulation factor deficiencies (STEP AC) in a double blind, randomized trial. Efficacy was determined by PT, PTT and clinical response to Test or Control FFP. **Methods:** FFP was treated using S-59 (150 µM) and UVA (~3 J/cm2) at 5 processing sites. Patients (pts) received FFP in support of acquired coagulation factor deficiencies for a 7-day period. Clinicians dosed study FFP per standard of care. Baseline pt samples were collected to assess the coagulopathy and to detect potential antibody formation to S-59 related plasma neoantigens. The primary end-point for the study was the PT/PTT response, normalized by FFP dose and body weight for the first study transfusion. Secondary end-point analyses included coagulation factor VII response to the first study transfusion, and PT/PTT responses to subsequent transfusions in the 7-day treatment period. All coagulation factor, S-59 and neo-antigenicity tests were performed by a central laboratory. **Results:** 121 pts were treated, while 116 pts were evaluable for the primary end-point. 48 evaluable pts were treated during orthotopic liver transplantation (OLT), while the remainder were supported before, and during other invasive procedures. There were 250 transfusion episodes in the study (123 Test; 127 Control). Overall, Test transfusions averaged 6.2 units/episode (±8.61; range of 1 to 66) versus a mean of 7.4 units/episode (±11.29; range of 1 to 56) in the Control arm. PT/PTT responses to the first transfusion were compared in all cases, and then stratified by those associated with OLT. Dose and weight-adjusted PT/PTT changes collected for the first study transfusion, in terms of sec•kg/mL, were compared using a 2-sample t-test.

All Patients

	INTERCEPT Plasma (N=58)			Control (N=58)			
	Pre-	Post-	Change (s•kg/mL)	Pre-	Post-	Change (s•kg/mL)	p Value
PT(s)	22.3±10.6	18.8±4.5	0.3±0.6	21.9±6.6	18.2±3.5	0.4±0.5	0.467
PTT(s)	42.5±13.4	39.3±11.2	0.3±0.8	43.6±16.8	41.4±23.0	-0.4±6.0	0.599

OLT Cases

	INTERCEPT Plasma (N=22)			Control (N=26)			
	Pre-	Post-	Change (s•kg/mL)	Pre-	Post-	Change (s•kg/mL)	p Value
PT(s)	19.4±7.2	17.7±5.5	0.0±0.2	19.9±7.2	16.5±3.3	0.1±0.4	0.330
PTT(s)	39.1±12.4	37.9±14.2	0.0±0.3	42.7±21.2	36.9±8.7	0.3±1.2	0.552

Factor VII response correlated with dose in both study arms. No antibodies to potential plasma neoantigens were detected. Peak S-59 levels were comparable to previous Helinx clinical trial results. Adverse events were comparable between INTERCEPT and Control arms (p=0.619). **Conclusions:** INTERCEPT Plasma used to support patients with acquired coagulopathies was comparable to conventional plasma with respect to PT/PTT response and safety in this population. The results of this clinical trial support the proposed use of INTERCEPT Plasma in a manner consistent with current practice for standard FFP.

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Pathogen Inactivated Platelets (plt) Using Helinx™ Technology (INTERCEPT plt) Are Hemostatically Effective in Thrombocytopenic Patients (tcp pts): The *SPRINT* Trial

Background: INTERCEPT plt (IP) are prepared with amotosalen HCl (S-59) & UVA light to inactivate a broad spectrum of pathogens & WBC in INTERCEPT platelet (plt) products (IP). *SPRINT* , a randomized double-blind controlled multi-center Phase III non-inferiority trial, compared the efficacy & safety of single donor plt (SDP) IP with untreated SDP (UP) in tcp pts requiring plt support. **Methods:** The 1° endpoint, the % of pts with clinically relevant bleeding (grade 2, WHO criteria) during a period of plt transfusion (txn) support, was assessed daily for 8 organ systems. Post txn bleeding & plt count increments (CI) for all on-protocol txn (2378 IP; 1799 UP) were compared by longitudinal regression analysis (LRA), with plt dose & other covariates. **Results:** Between 7/1999 & 1/2001, 671 pts were randomized at 12 US sites to receive up to 28 days of plt txn with IP or UP. 645 pts received $\geq$1 plt txn (ITT population). 280 (88%) IP and 294 (90%) UP pts completed the txn period. Age, race, gender, 1° diagnosis, and reason for plt txn support were similar between groups. 91% of IP & 95% UP txn were on-protocol. Mean days of storage was 3.4 for IP & 3.6 for UP.

Endpoints	INTERCEPT (IP) (n=318)	Untreated (UP) (n=327)	P value (95% CI of Diff)
% Pts with grade 2 bleeding	58	57	0.80 (-6.6%, 8.6%)
% Pts with grade 3 & 4 bleeding	4	6	0.24 (-5.4%, 1.4%)
Pre-txn plt count (x10 ^{9} /L)	15	15	0.88
1 Hr Post-txn plt count (x10 ^{9} /L)	37	50	<0.001
24 Hr Post-txn plt count (x10 ^{9} /L)	28	36	<0.001

1 Hr Corrected CI (CCI, × 10^3)	11.1	16.0	<0.001
24 Hr CCI (x 10^3)	6.7	10.1	<0.001
Mean transfused plt dose (x 10^{11})	3.7	4.0	<0.001
% Plt doses <3 × 10^{11}	20	12	<0.001
Mean total dose plts (x 10^{11})	29.4	24.1	0.01
Mean no. plt txn (range)	8.4 (1,49)	6.2 (1,48)	<0.001
Mean interval between plt txn (days)	1.9	2.4	<0.001
Mean duration plt support (days)	11.8	10.6	0.08
% Plt txn with txn reactions	3.0	4.4	0.02
Mean no. RBC txn	5.6	5.0	0.12

Mean days of grade 2 bleeding, adjusted for days of plt txn, was similar for IP & UP, 0.19 & 0.16, respectively (p=0.08). By LRA, comparable doses of IP & UP resulted in lower mean 1 & 24 hr CI for IP, by 10 & 6.6 × 10^9 plt/L, respectively (p<0.001) but post-txn bleeding (≥ grade 2) was similar for IP & UP pts and independent of dose. 21% of IP & 7% of UP pts had 2 successive 1 hr CCI < 5 x 10^3 (p<0.001). These low CCI were transient (5.9% of IP & 8.7% of UP pts had 1 hr CCI persistently < 5 × 10^3 thru end of txn period) and not immune-mediated. LCA was positive in 16% of IP & 22% of UP pts; anti-plt antibody was present in 6% of IP & 9% of UP pts. No antibodies to S-59 neoantigens were detected. **Conclusions:** INTERCEPT platelets were as effective as conventional plt for prevention & treatment of bleeding in tcp pts requiring multiple plt txns. However IP resulted in lower CI & CCI, more IP txn & shorter txn intervals. LRA suggests increased doses of IP per txn can improve the CI. INTERCEPT platelets provide pathogen inactivation while maintaining hemostatic efficacy.