CERUS CORP

FORM 8-K
(Current report filing)

Filed 01/04/06 for the Period Ending 12/30/05

Address	2550 STANWELL DRIVE CONCORD, CA 94520
Telephone	9252886000
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Symbol	CERS
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
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): **December 30, 2005**

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**

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 December 30, 2005, Cerus Corporation (the "Company") announced that it has submitted a CE Mark application for approval to market its INTERCEPT Blood System for plasma in Europe. A copy of the Company's press release, entitled "Cerus Submits CE Mark Application for European Approval of the INTERCEPT Blood System for Plasma," is furnished as Exhibit 99.1 hereto.

In addition, on December 30, 2005, the Company announced that it has submitted an investigational new drug application to the U.S. Food and Drug Administration to initiate a Phase 1 safety trial for CRS-100, a *Listeria* -based immunotherapeutic designed to treat patients with cancer that has metastisized to the liver. A copy of the Company's press release, entitled "Cerus Submits IND Application for CRS-100 to FDA," is furnished as Exhibit 99.2 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, dated December 30, 2005, entitled "Cerus Submits CE Mark Application for European Approval of the INTERCEPT Blood System for Plasma."

99.2 Press Release, dated December 30, 2005, entitled "Cerus Submits IND Application for CRS-100 to FDA."

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: January 3, 2006

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release, dated December 30, 2005, entitled “Cerus Submits CE Mark Application for European Approval of the INTERCEPT Blood System for Plasma.”
99.2	Press Release, dated December 30, 2005, entitled “Cerus Submits IND Application for CRS-100 to FDA.”

Exhibit 99.1

Contacts:

Ruey-Li Hwang
Corporate Communications
Cerus Corporation
(925) 288-6017

CERUS SUBMITS CE MARK APPLICATION FOR EUROPEAN APPROVAL OF THE INTERCEPT BLOOD SYSTEM FOR PLASMA

CONCORD, CA, December 30, 2005 - Cerus Corporation (NASDAQ: CERS) announced today the submission of a CE Mark application for approval to market the INTERCEPT Blood System for plasma in Europe. The system, which is being jointly developed by Cerus and Baxter Healthcare Corporation, is designed to reduce the risk of transfusion-transmitted diseases. It inactivates pathogens such as HIV, hepatitis B and C viruses, bacteria, and parasites that may be present in donated plasma intended for transfusion.

"We believe in pathogen inactivation and its potential to improve the safety of the global blood supply," said Claes Glassell, president and CEO of Cerus Corporation. "This filing is one more step in our plan to commercialize the INTERCEPT Blood System for all three components: platelets, plasma, and red blood cells."

While donated plasma is generally tested for a limited number of specific pathogens, testing does not eliminate the risk of viral or bacterial contamination. The INTERCEPT Blood System for plasma is being developed to enhance the safety of plasma transfusions by targeting the nucleic acids of a broad spectrum of viruses, bacteria and other pathogens.

ABOUT THE INTERCEPT BLOOD SYSTEM

Cerus Corporation is collaborating with subsidiaries of Baxter International Inc. on the INTERCEPT Blood System, designed to target and inactivate blood-borne pathogens, such as HIV and hepatitis B and C, as well as harmful white blood cells, while leaving intact the therapeutic properties of donated blood components. Based on Cerus' Helinx technology, the INTERCEPT Blood System inactivates a broad array of pathogens and offers the potential to inactivate untested-for and emerging pathogens before they become a major transfusion risk to patients. The INTERCEPT Blood System for plasma has been evaluated in three Phase III clinical trials, and a CE Mark application for approval in Europe has

been submitted. The INTERCEPT Blood System for platelets is approved for use in the European Union.

ABOUT CERUS

Cerus Corporation is developing novel products for cancer, infectious disease and blood safety based on multiple, innovative technology platforms. The company is building a pipeline of next generation cancer immunotherapies by combining its proprietary attenuated *Listeria* vector platform with promising disease antigens. These products are designed to stimulate innate and T cell immune pathways, generating highly potent anti-tumor responses. The company's KBMA vaccine technology has potential broad applications against multiple pathogens. Cerus is applying its Helinx technology to develop the INTERCEPT Blood System, which is designed to enhance the safety of blood components through pathogen inactivation. The company's strategy is to leverage the broad potential of its technologies and products through alliances. Cerus' partners to date include MedImmune and Johns Hopkins University for cancer immunotherapy, and Baxter International and BioOne Corporation for the INTERCEPT Blood System.

Helinx is a trademark of Cerus Corporation.

Baxter and INTERCEPT are trademarks of Baxter International, Inc.

Statements in this news release regarding potential efficacy and safety of products, product development and commercial 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 uncertainties inherent in developing biotechnology products based on new technologies, the timing and results of clinical trials and other development activities, market acceptance of Cerus Corporation's products, actions by regulatory authorities at any stage of the development process, the availability of governmental or third party reimbursement for the use of Cerus Corporation's products, the size of the market for the company's products, competitive conditions, manufacturing capabilities, and other factors discussed in the company's Form 10Q for the third quarter of fiscal 2005, as well as in other reports filed with the Securities and Exchange Commission. The company assumes no obligation to update any forward-looking statements.

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Exhibit 99.2

Contact:

Ruey-Li Hwang
Corporate Communications
Cerus Corporation
(925) 288-6017

CERUS SUBMITS IND APPLICATION FOR CRS-100 TO FDA

CONCORD, CA, December 30, 2005 - Cerus Corporation (NASDAQ: CERS) today announced that it has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) to initiate a Phase 1 safety trial for CRS-100, a *Listeria* -based immunotherapeutic designed to treat patients with cancer that has metastasized to the liver.

Preclinical studies demonstrate the potential of Cerus' proprietary *Listeria* strain (CRS-100) to stimulate a potent immune response against certain cancers in the liver. Data from some of these studies have been published in peer-reviewed journals, including a paper in the September 21, 2004, issue of the *Proceedings of the National Academy of Sciences* . Subject to FDA concurrence, Cerus intends to initiate a Phase I clinical trial in collaboration with investigators at leading cancer centers in the United States during the first half of 2006.

"The filing of our first IND in cancer immunotherapy using our proprietary *Listeria* platform is an important milestone in Cerus' strategic development ," said Claes Glassell, president and CEO of Cerus Corporation. " We believe that our *Listeria* platform will lead to more potent and effective therapies that stimulate both innate and adaptive immune responses to target cancer cells. I am very proud of the remarkable progress our team has recently made on our immunotherapy programs."

Colorectal cancer, which is the second most common cause of cancer death in the United States, often metastasizes to the liver, contributing to its morbidity. Despite recent advances, metastasized colorectal cancer remains a significant unmet medical need.

ABOUT CERUS

Cerus Corporation is developing novel products for cancer, infectious disease and blood safety based on multiple, innovative technology platforms. The company is building a pipeline of next generation cancer immunotherapies by combining its proprietary attenuated *Listeria* vector platform with promising disease antigens. These products are designed to stimulate innate and T cell immune pathways, generating highly potent anti-tumor responses. Cerus is applying its Helinx technology to develop the INTERCEPT

Blood System, which is designed to enhance the safety of blood components through pathogen inactivation. The company's strategy is to leverage the broad potential of its technologies and products through alliances. Cerus' partners to date include MedImmune and Johns Hopkins University for cancer immunotherapy, and Baxter International and BioOne Corporation for the INTERCEPT Blood System.

Statements in this news release are forward-looking statements that involve risks and uncertainties, including statements concerning the potential safety and efficacy of product candidates and the potential of the company's Listeria based immunotherapy technology. Actual results could differ materially from the above forward-looking statements as a result of certain factors, including the risks and uncertainties inherent in developing biotechnology products based on new technologies, the timing and results of clinical trials and other development activities, market acceptance of our products, actions by regulatory authorities at any stage of the development process, the availability of governmental or third party reimbursement for the use of our products, the size of the market for our products, competitive conditions, manufacturing capabilities, our reliance on our relationship with partners and other factors discussed in the company's Form 10-Q for the third quarter of fiscal 2005, as well as in other reports filed from time to time with the Securities and Exchange Commission. The company assumes no obligation to update any forward-looking statements.

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