CERUS CORP

FORM 8-K
(Current report filing)

Filed 06/05/03 for the Period Ending 06/04/03

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Telephone	9252886000
CIK	0001020214
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): June 4, 2003

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 June 4, 2003, Cerus Corporation (the "Company") and Baxter International, Inc. ("Baxter") announced that the Company and Baxter reached agreement with the U.S. Food and Drug Administration on steps for regulatory approval for their pathogen inactivation system for platelets. A copy of the Company's press release is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 7. Exhibits.

Exhibit Number	Description of Exhibit
99.1	Press Release, dated June 4, 2003, entitled "Baxter and Cerus Reach Agreement With FDA On Steps To Gain Regulatory Approval For Innovative Pathogen Inactivation System."

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: June 4, 2003

By: /s/ Gregory W. Schafer
Gregory W. Schafer
Vice President, Finance and
Chief Financial Officer

Index to Exhibits

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99.1	Press Release, dated June 4, 2003, entitled “Baxter and Cerus Reach Agreement With FDA On Steps To Gain Regulatory Approval For Innovative Pathogen Inactivation System.”

Exhibit 99.1

For Cerus
Media and Investor Relations:
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Lisa Luttinger, (925) 288-6036

For Baxter
Media:
Tanya Tyska, (847) 270-4918, North America
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BAXTER AND CERUS REACH AGREEMENT WITH FDA ON STEPS TO GAIN REGULATORY APPROVAL FOR INNOVATIVE PATHOGEN INACTIVATION SYSTEM

DEERFIELD, ILL. and CONCORD, CALIF. , June 4, 2003—Subsidiaries of Baxter International Inc. (NYSE: BAX) and Cerus Corporation (Nasdaq: CERS) announced today that the companies reached agreement with the U.S. Food and Drug Administration (FDA) on steps for regulatory approval for their pathogen inactivation system for platelets.

Baxter and Cerus have been in ongoing discussions with the FDA throughout the submission of their modular application for their pathogen inactivation system for platelets. The steps that have been agreed upon include conducting a supplemental platelet transfusion study and performing additional analysis of the U.S. Phase III clinical trial data. The clinical trial will be carried out using the commercial set and will provide additional data to address FDA questions related to platelet performance in the U.S. Phase III clinical trial. This commercial set has previously undergone successful European clinical testing and is now commercially available in Europe.

"We are pleased to have reached this agreement, and with these two additional steps we now have a clear path to complete the regulatory submission process," said Stephen T. Isaacs, president and chief executive officer of Cerus. "Our resolve is strong to make the blood supply as safe as possible and we are committed to moving expeditiously to bring this innovative technology to the marketplace."

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Greg Young, corporate vice president and president of Baxter's Transfusion Therapies business said, "We continue to work collaboratively with the FDA throughout this process, and accept the responsibility that comes with being leaders looking to bring an innovative critical care therapy to the marketplace. Baxter and Cerus are dedicated to taking all necessary steps required by the FDA to definitively demonstrate that our pathogen inactivation system will offer an additional layer of safety to the nation's blood supply."

The two companies expect to complete the additional steps in the next 15-18 months with regulatory submission to follow shortly thereafter.

Baxter and Cerus' pathogen inactivation system is being developed to potentially protect patients by reducing the risk of transfusion-transmitted diseases. The system is designed to go a step beyond current blood safety measures, which *test* for certain infectious diseases, by *inactivating* a broad spectrum of pathogens, including viruses, bacteria, parasites and potentially harmful donor white blood cells in blood components intended for transfusion. For platelets, the system uses a light-activated compound that is designed to target and inactivate pathogens containing DNA and RNA, such as HIV and hepatitis B and C, and to render them harmless by preventing them from replicating.

In 2002 the companies received regulatory approval in Europe for the technology, known as the INTERCEPT Blood System for platelets. The INTERCEPT Blood System is the only pathogen inactivation system that is approved and available for use in Europe with platelets. Patients undergoing chemotherapy, heart bypass surgery and other procedures that require platelet transfusions are expected to benefit from this technology.

Cerus and Baxter are conducting clinical trials of their pathogen inactivation system for use with plasma and red blood cells for transfusion, making their system the only pathogen inactivation technology currently being developed for use with all primary blood components.

Baxter International Inc. assists health-care professionals and their patients with treatment of complex medical conditions, including cancer, hemophilia, immune disorders, kidney disease

and trauma. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives. For more information about Baxter, please visit www.baxter.com.

Cerus Corporation is developing medical systems and therapeutics to provide safer and more effective options to patients. The company is developing products based on its proprietary Helinx® technology for controlling biological replication. Cerus' most advanced programs are focused on systems to enhance the safety of the world's blood supply. The INTERCEPT Blood System, which is being developed in collaboration with subsidiaries of Baxter International Inc. is based on the company's Helinx technology. The Concord, California-based company also is pursuing therapeutic applications of Helinx technology to treat and prevent serious diseases.

Statements in this news release regarding regulatory filings, 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 uncertainty of the timing and results of clinical trials and other development activities, actions by regulatory authorities at any stage of the development and commercialization process, additional financing activities, manufacturing, market acceptance of any products, competitive conditions and other factors discussed in the companies' most recent filings with the Securities and Exchange Commission.

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