CERUS CORP
Form 10-K405
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# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2001**

**OR**

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**Commission file number 0-21937**

# CERUS CORPORATION

(Exact name of registrant as specified in its charter)

| **Delaware** | **68-0262011** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (IRS Employer Identification No.) |
| **2411 Stanwell Dr.**<br>**Concord, California** | **94520** |
| (Address of principal executive offices) | (Zip Code) |

**(925) 288-6000**

(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:**
**None**

**Securities registered pursuant to Section 12(g) of the Act:**
**Common Stock, par value $.001 per share**

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

The approximate aggregate market value of the common stock held by non-affiliates of the registrant, based upon the $47.03 closing price of the common stock reported on the Nasdaq National Market on February 28, 2002, was $476,468,361.

As of February 28, 2002, there were 15,754,460 shares of the registrant's common stock outstanding.

Portions of the registrant's definitive proxy statement to be issued in connection with its 2002 annual meeting of stockholders are incorporated by reference to Part III of this report.

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## PART I

*This report contains forward-looking statements. These forward-looking statements are based on Cerus Corporation's current expectations about its business and industry, and include, but are not limited to, statements concerning Cerus' plans or expectations concerning development and commercialization of its current product candidates; conduct of clinical trials of its product candidates; regulatory approvals; its ability to address certain markets; manufacturing and supply for its clinical trial and commercial requirements; reliance on a third party for a marketing, sales and distribution capability; and evaluation of additional product candidates for subsequent clinical and commercial development. In some cases, these statements may be identified by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of such terms and other comparable terminology. In addition, statements that refer to expectations or other characterizations of future events or circumstances are forward-looking statements. These statements involve known and unknown risks and uncertainties that may cause Cerus' or its industry's results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences*

*include, among others, those discussed under the captions "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements not specifically described above also may be found in these and other sections of this report. Cerus undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of this report.*

Helinx is a trademark of Cerus Corporation. INTERCEPT Blood System, INTERCEPT Platelet System, INTERCEPT Plasma System, INTERCEPT Red Blood Cell System and INTERSOL are trademarks of Baxter International, Inc.

**Item 1.** ***Business***

**Overview**

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 blood products used for transfusion. The INTERCEPT Blood Systems, based on the company's Helinx technology, are designed to inactivate viruses, bacteria, other pathogens and white blood cells. Cerus also is pursuing therapeutic applications of Helinx technology to treat and prevent serious diseases.

Cerus is developing the INTERCEPT Platelet System, INTERCEPT Plasma System and INTERCEPT Red Blood Cell System with its development and commercialization partner, Baxter Healthcare Corporation. The INTERCEPT Blood Systems are intended 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 the blood components. The INTERCEPT Blood Systems inactivate a broad array of pathogens and have the potential to reduce the risk of transmission of pathogens for which testing is not completely effective or is not currently performed. Cerus believes that the INTERCEPT Blood Systems also have the potential to inactivate new pathogens before they are identified and before tests are developed to detect their presence in donated blood. An estimated four million units of platelets, seven million units of fresh frozen plasma and 37 million units of red blood cells are transfused annually in the United States, Western Europe and Japan.

Cerus and Baxter have submitted regulatory applications seeking CE Mark approval in Europe and marketing approval in Australia and Canada and have begun the regulatory submission process in the United States for approval of the INTERCEPT Platelet System. In addition, the companies are preparing the U.S. regulatory submission for approval of the INTERCEPT Plasma System, which will be followed by a CE Mark application for this product. The INTERCEPT Red Blood Cell System is in pivotal Phase III clinical trials in the United States. Cerus' allogeneic cellular immune therapy (ACIT)



program, designed to improve the outcome of bone marrow transplantation procedures through use of T-cells treated with the Helinx technology, is in Phase I clinical trials. Cerus' Epstein-Barr Virus (EBV) cellular vaccine program is in pre-clinical development.

Cerus is conducting product development and commercialization activities with Baxter pursuant to agreements for the development, manufacturing and marketing of the INTERCEPT Blood Systems. These agreements provide for Baxter and Cerus to generally share development expenses, for Baxter's exclusive right and responsibility to market the systems worldwide and for Cerus to receive a share of the gross profits from the sale of the systems.

Cerus was incorporated in California in 1991 and reincorporated in Delaware in 1996.

**Industry Background**

*Blood Supply Market.* Blood transfusions are required to treat a variety of medical conditions, including anemia, low blood volume, surgical bleeding, trauma, acquired and congenital bleeding disorders and chemotherapy-induced blood deficiencies. Worldwide, over 90 million whole blood donations occur each year. Approximately 40-50 million of those donations occur in North America, Western Europe and Japan, the primary geographical markets for the INTERCEPT Blood Systems.

Whole blood is composed of plasma, the liquid portion of blood containing essential clotting proteins, and three cellular blood components: platelets, red blood cells and white blood cells (leukocytes). Platelets are essential to coagulation, while red blood cells carry oxygen to tissues and carbon dioxide to the lungs. White blood cells play a critical role in immune and other defense systems, but can cause harmful transfusion-related immune reactions in, or transmit disease to, transfusion recipients.

Blood collection centers periodically experience shortages of critical blood components due to temporary increases in demand, reduced donor availability during holiday periods and the limited shelf life of cellular blood components. To efficiently allocate the limited available blood supply and to optimize transfusion therapy, essentially all donated blood is separated into platelets, plasma and red blood cells. These blood components are obtained either by manually processing donor units of whole blood or by apheresis, an automated process by which a specific blood component is separated and collected from the donor's blood while the other components are simultaneously returned to the donor.

Patients requiring transfusions typically are treated with one or more specific blood components required for their particular deficiency, except in cases of rapid, massive blood loss, in which whole blood may be transfused. Platelets often are used to treat cancer patients following chemotherapy or organ transplantation. Red blood cells frequently are administered to patients with trauma or surgical bleeding, acquired chronic anemia or genetic disorders, such as sickle cell anemia. Plasma used for transfusions is stored in frozen form and is referred to as fresh frozen plasma, or FFP. FFP generally is used to control bleeding. Plasma also can be separated, or "fractionated," into different products that are administered to expand blood volume, fight infections or treat diseases such as hemophilia.

*Blood Supply Contaminants.* A primary goal of every blood collection center is to provide blood components for transfusion that are free of viruses, bacteria and other pathogens. Despite improvements in donor screening and in the testing and processing of blood, patients receiving blood transfusions still face a number of significant risks from blood contaminants, as well as adverse immune and other transfusion-related reactions induced by white blood cells. Viruses, such as hepatitis B (HBV), hepatitis C (HCV), human immunodeficiency virus (HIV), cytomegalovirus (CMV) and human T-cell lymphotropic virus (HTLV), can present life-threatening risks. In addition, bacteria, the most common agents of transfusion-transmitted disease, can cause complications, such as sepsis, which can result in serious illness or death. Many other agents can transmit disease during transfusion, including the protozoa that cause malaria and Chagas' disease.



Infectious pathogens are not the only cause of adverse events arising from the transfusion of blood components. White blood cells present in a blood unit can multiply after transfusion, mounting a potentially fatal graft-versus-host immune response against the recipient. Similarly, alloimmunization, an immune response that can develop from repeated exposure to transfused white blood cells, can significantly reduce the efficacy of subsequent transfusions. Moreover, white blood cells themselves may harbor and transmit bacteria and infectious viruses, such as HIV, CMV and HTLV.

Emerging and unidentified pathogens also present a threat to the blood supply, a problem illustrated by HIV. It is estimated that HIV was present in the blood supply for at least seven years before it was identified as the causative agent of AIDS and at least eight years before a test was commercially implemented to detect the presence of HIV antibodies in donated blood. During those years, many transfusion recipients were infected with the virus, including approximately 70% of patients with severe hemophilia. In addition, new variants of HIV and other viruses, such as hepatitis G, have been identified. Transfused blood is not routinely tested for these emerging viruses, despite the potential risk to transfusion recipients.

The risk of transmission of pathogens from an infected donor is compounded by a number of factors. If a unit of blood contains an infectious pathogen, dividing the blood into its components may expose three or more patients to the pathogen in that unit. Blood products are commonly pooled from several donors to form a single therapeutic dose, which increases the recipient's risk of infection. Similarly, patient populations that require frequent transfusions, such as patients with cancer, suppressed immune systems, congenital anemias and kidney and liver disorders, experience a heightened risk of infection due to multiple donor exposures.

*Current Approaches to Address Blood Supply Contamination.* Public awareness of the significant rates of hepatitis, HIV and other viral transmission from blood transfusions has led to expanded efforts to improve the safety of the blood supply. For many years, the only approach available to reduce the risk of transmission of diseases was donor screening interviews. In addition to required donor screening, diagnostic tests have been developed to detect the presence of certain infectious pathogens known to be transmitted in blood. However, there remain a number of other blood-borne pathogens for which tests are not routinely administered, and for many of these, no tests have been developed.

Although donor screening and diagnostic testing of donated blood have been successful in reducing the incidence of transmission of some of these known pathogens, these methods have significant limitations. Tests are currently performed for only a limited number of blood-borne pathogens. Moreover, current methods of testing are not completely effective, which can lead to the release of contaminated blood into transfusion inventory. Most tests used in blood centers in the United States are intended to detect antibodies directed against a pathogen or surface antigens. All tests currently in use by blood centers can fail if performed during the "infectivity window," that is, early in the course of an infection before agents appear in detectable quantities. Nucleic acid testing for HIV and hepatitis C is mandatory in blood centers in Europe, and is used by most blood centers in the United States. Although nucleic acid testing is more effective at detecting specific pathogens in earlier stages of infection in a donor, it does not close the infectivity window completely. For example, a transfusion recipient in the United States recently became infected with HIV from a blood transfusion for which nucleic acid testing failed to detect the virus. Furthermore, nucleic acid

testing, like other testing currently performed on donated blood, provides limited benefit as it is effective only for specific viruses for which the testing is performed. In addition, tests for viral infection may be ineffective in detecting a genetic variant of the virus that the test was not developed to detect. For instance, certain strains of HIV, such as Subtype O, sometimes are not detected in standard HIV tests. Finally, there are no current tests available to screen effectively for many emerging pathogens, and testing cannot be performed for pathogens that have yet to be identified. As a result of these limitations, a number of infectious pathogens still pass into the blood supply.



In light of these continuing concerns, many patients have attempted to mitigate the risks of transfusion through "autologous donation," which is the donation of the patient's own blood for anticipated future use, or, where autologous donation is impracticable, through the designation of donors such as family members. Although autologous donations eliminate many risks, the blood collected is still subject to the risk of bacterial growth during storage and is rarely available in emergency situations or when a patient is chronically ill. In addition, the statistical incidence of infected units from designated donor blood has been found to be as high as in random donor units.

Blood centers and health care providers have initiated additional procedures in an effort to address pathogen transmission issues. For example, platelet apheresis is sometimes used to limit donor exposure from pooled, manually collected platelets. In addition, blood centers may quarantine single donor plasma apheresis units until after the infectivity window has elapsed, followed by confirmatory retesting of the donor, if the donor is available, to help verify the safety of the donated plasma. However, quarantining plasma is expensive, and inventory is difficult to manage. Moreover, a quarantine cannot be used with platelets and red blood cells because these components have shelf lives that are shorter than the infectivity window related to antibody production. No commercial processes are currently available to eliminate pathogens in platelets and red blood cells. Two pathogen inactivation methods are used commercially for FFP: treatment with solvent-detergent and methylene blue, which is used in Europe. Because the solvent-detergent process pools hundreds of units of plasma, the potential risk of transmitting pathogens not inactivated by the process is increased. Methylene blue has not been shown to be effective in the inactivation of intracellular viruses and bacteria.

Some blood centers are currently using gamma irradiation to inactivate white blood cells. This nonspecific method has a narrow range of efficacy: insufficient treatment can leave viable white blood cells in the blood, while excessive treatment can impair the therapeutic function of the desirable blood components being transfused. White blood cell depletion by filtration decreases the concentration of these cells in transfusion units, but does not inactivate or completely eliminate white blood cells or inactivate the immunological functions of the cells not removed by the filtration process.

*Economic Costs of Blood Supply Contamination.* In economically developed countries, many of the tests and inactivation measures described above are mandated by regulatory agencies, resulting in a safer and more uniform blood supply, but also significantly increasing costs of processing and delivering blood products.

Moreover, the development and widespread implementation of testing for many unusual or low-incidence pathogens is not cost-effective or practical. For example, the development of tests to detect the presence of all forms of harmful bacteria would be extremely expensive. As a result, the only test regularly conducted to detect the presence of bacteria is the test for the bacterium that causes syphilis.

The continuing risk of transmission of serious diseases through transfusion of contaminated blood components from both known and unknown pathogens, together with the limitations of current approaches to providing a safe blood supply, have created the need for a new approach to pathogen inactivation that is safe, easy to implement and cost-effective. Cerus believes that such an approach should be effective in inactivating a broad spectrum of clinically significant pathogens, preserve the therapeutic properties of the blood components and be safe for use.

**INTERCEPT Blood Systems and Helinx Technology**

Cerus and its development and commercialization partner, Baxter, are developing INTERCEPT Blood Systems to prevent the transmission of infectious diseases through blood transfusions. The INTERCEPT Blood Systems employ Cerus' proprietary nucleic-acid targeting Helinx technology. Cerus has conducted studies that have demonstrated the ability of the Helinx technology to inactivate a broad

array of viral, bacterial and parasitic pathogens that may be transmitted in blood transfusions. Cerus believes that the mechanism of action of its Helinx technology provides the potential to inactivate many new pathogens before they are identified and before tests are developed to detect their presence in the blood supply. Because INTERCEPT Blood Systems are designed to inactivate rather than merely test for pathogens, the systems also have the potential to reduce the risk of transmission of pathogens that would otherwise remain undetected by testing.

Helinx technology prevents the replication of DNA or RNA, which is present in viruses, bacteria and other pathogens. Therapeutic blood components (platelets, FFP and red blood cells) do not contain nuclear DNA or RNA the targets for the Helinx technology. When Cerus' proprietary inactivation compounds are combined with the blood components for treatment, they cross bacterial cell walls or viral membranes and move into the interior of the nucleic acid structure. When subsequently activated by an energy source, such as light, the compounds bind to the nucleic acid of the viral or bacterial pathogen, preventing replication of the nucleic acid. This process prevents infection because a virus, bacteria or other pathogen must replicate its DNA or RNA to proliferate and cause infection. The Helinx compounds react in a similar manner with the nucleic acid in white blood cells, inhibiting the activity that is responsible for certain adverse immune and other transfusion-related reactions. These compounds are designed to react with nucleic acid only during the pathogen inactivation process and not after the treated blood component is transfused.

INTERCEPT Blood Systems are being designed to integrate into current blood collection, processing and storage procedures. Furthermore, Cerus believes that the use of INTERCEPT Blood Systems, in addition to eliminating the need to implement costly new testing procedures, could potentially lead to a reduction in the use of certain costly procedures that are currently employed in blood component transfusions, such as gamma irradiation, CMV testing and white blood cell filtration.

**Cerus Strategy**

Cerus' objective is to develop medical systems and therapeutics that provide safer and more effective treatment options to patients. The INTERCEPT Blood Systems, based on the company's Helinx technology, are designed to inactivate viruses, bacteria, other pathogens and harmful white blood cells in blood components for transfusion. Cerus also is pursuing therapeutic applications of Helinx technology to treat and prevent serious diseases. Cerus' strategy incorporates the following key elements:

*Establish INTERCEPT Blood Systems as the Standard of Care.* Domestically, the target customers for the INTERCEPT Blood Systems are the approximately 105 community blood center organizations that collect approximately 85% of blood in the United States. There is an even greater concentration among blood centers in foreign countries. Baxter has a significant marketing presence in these blood centers in the United States and abroad. In addition, Cerus has developed strong relationships with prominent transfusion medicine experts in a number of these centers as well as in the broader medical communities worldwide. Cerus intends to work with these experts to encourage support for the adoption of the INTERCEPT Blood Systems as the standard of care.

*Use Strategic Alliances.* Cerus has received significant development funding from Baxter, and intends to leverage Baxter's manufacturing, marketing and distribution expertise and resources. Cerus believes that Baxter's established position as a manufacturer and leading supplier of devices, disposables and other products related to the transfusion of human blood products can provide Cerus with access to an established marketing, sales and distribution network. The INTERCEPT Blood Systems are being designed to integrate into Baxter's current product line and into current blood collection, processing and storage processes. Cerus has also entered into a collaborative agreement with, and received development funding from, the Pharmaceutical Division of Kirin Brewery Co., Ltd. to develop and market products for stem cell transplantation based on Cerus' Helinx technology. Under



this agreement, Cerus and Kirin will jointly develop the products. Kirin will market any approved products resulting from the collaboration in the Asia-Pacific region, including Japan, China, Korea and Australia, and Cerus will receive a specified share of product revenue. Cerus retains all marketing rights in the rest of the world, including the United States and Europe. Cerus intends to continue to develop its products together with partners that can provide direct funding and manufacturing, marketing and distribution resources and expertise.

*Protect and Enhance Proprietary Position.* Cerus believes that the protection of its proprietary technologies is important to its business prospects and that its intellectual property position may create competitive barriers to entry into the blood component treatment market. Cerus currently holds issued and allowed patents covering a number of fundamental aspects of its Helinx technology and its blood component treatment system technology. Cerus intends to continue to pursue its patent filing strategy and to vigorously defend its intellectual property position against infringement.

*Leverage Expertise and Helinx Technology.* Cerus is using its broad expertise in nucleic acid chemistry to develop additional products, beyond the INTERCEPT Blood Systems. Cerus believes that its nucleic acid-targeting Helinx technology has potential application in a number

of health and research-related fields, such as bone marrow transplantation, cancer, cellular vaccines and hematologic and proliferative disorders.

**Product Development**

Cerus is developing treatment systems to inactivate infectious pathogens and harmful white blood cells in platelets, FFP and red blood cells and to improve the outcomes of bone marrow transplantation procedures. Cerus has incurred research and development expenses of $48.2 million, $34.8 million and $22.5 million for the years ended December 31, 2001, 2000 and 1999, respectively. The following table identifies Cerus' product development programs:

| Program | Therapeutic Indication | Cerus Product In Development | Development Status | Partner |
|---|---|---|---|---|
| Platelets | Surgery, cancer chemotherapy, transplantation, bleeding disorders | INTERCEPT Platelet System | Regulatory applications for CE Mark approval in Europe and for marketing approval in Australia and Canada submitted; regulatory application process underway in the United States | Baxter |
| Plasma (FFP) | Surgery, transplantation, bleeding disorders | INTERCEPT Plasma System | Phase IIIa and IIIb clinical trials completed; Phase IIIc clinical trial enrolling patients | Baxter |
| Red Blood Cells | Surgery, transplantation, anemia, cancer chemotherapy, trauma | INTERCEPT Red Blood Cell System | Phase III clinical trials enrolling patients | Baxter |
| Allogeneic Cellular Immunotherapy (ACIT) | Allogeneic bone marrow transplant to treat leukemia and lymphoma | T-Cells Treated with the Helinx Technology | Phase I clinical trials | Kirin |



*Clinical Trial Design.* Cerus conducts clinical trials using several designs. In a controlled study, treated and untreated blood components are administered to subjects who are randomly assigned to either a test group or a control group, and the results are compared. In a cross-over study, each subject receives both treated and untreated blood components in random order. To avoid bias in reporting side effects, studies are usually blinded. In a single-blind study, subjects are not told whether they are receiving treated or untreated blood components. In a double-blind study, neither the subject (patient) nor the investigator (physician) knows whether the subject is receiving treated or untreated blood components.

***Platelet Program***

*Platelet Usage and Market.* Platelets are cellular components of blood that are an essential part of the clotting mechanism. Platelets facilitate blood clotting and wound healing by adhering to damaged blood vessels and to other platelets. Platelet transfusions are used to prevent or control bleeding in platelet-deficient patients, such as those undergoing chemotherapy or organ transplantation. Transfusion units of platelets are obtained either by combining the platelets from four to six whole blood donations (pooled random donor platelets), or in an automated procedure in which a therapeutic dose of platelets is obtained from a single donor (apheresis or single donor platelets). A principal motivation for platelet apheresis is to limit donor exposure from pooled, manually collected platelets. Platelet transfusions may also require additional testing and processing procedures. Cerus believes that the INTERCEPT Platelet System may reduce the need for many of these procedures and associated costs.

Cerus estimates the production of platelets in 2001 to have been 1.9 million transfusion units in North America, 1.3 million transfusion units in Western Europe and 0.7 million transfusion units in Japan. In the United States, based on a study of six blood centers conducted in October 1998 on behalf of Cerus, the estimated base cost for a transfusion unit of apheresis platelets ranges from approximately $400 to $550, and the estimated base cost for a transfusion unit of random donor platelets ranges from approximately $170 to $330. These estimates include donor screening and diagnostic tests, such as those for HIV, HTLV, HBV and HCV. Blood centers may also charge up to $210 per unit for additional procedures, such as gamma irradiation and CMV screening. The frequency of use and additional charge for each procedure vary widely.

*INTERCEPT Platelet System.* The INTERCEPT Platelet System uses Cerus' Helinx compound, amotosalen (formerly S-59), which is a synthetic small molecule from a class of compounds known as psoralens. The selection of amotosalen was based on an extensive analysis of the compound's safety, its ability to inactivate pathogens and harmful white blood cells and the preservation of platelet and plasma coagulation factor function following treatment with amotosalen.

When illuminated, amotosalen undergoes a specific and irreversible chemical reaction with DNA and RNA. This chemical reaction renders a broad array of pathogens and cells incapable of replication. A virus, bacteria or other pathogenic cell cannot cause an infection if it cannot replicate. A similar reaction with the nucleic acid in white blood cells inhibits the activity that is responsible for certain adverse immune and other transfusion-related reactions. Studies conducted by Cerus with pre-clinical models have indicated that, following transfusion, the amotosalen and, following illumination, its breakdown products are rapidly metabolized and excreted. As a further safety measure, the INTERCEPT Platelet System employs a removal process designed to reduce the amount of residual amotosalen and breakdown products following treatment.

Cerus and Baxter have designed the INTERCEPT Platelet System for use in the blood center. The system consists of a disposable processing set, containing the amotosalen compound and a compound absorption device (CAD), and an illumination device to deliver light to trigger the inactivation reaction. The system involves the collection of the platelets, as normally performed, with two-thirds of the plasma replaced by a platelet additive solution, called INTERSOL, followed by transfer of the platelets



through a pouch containing the amotosalen compound into a container. The mixture of platelets, amotosalen and INTERSOL is then illuminated for approximately three to five minutes. Following the CAD treatment, which takes approximately four to six hours, the platelets are transferred to the final storage container.

*Development Status.* In Europe, Cerus has completed its 103-patient Phase III EuroSPRITE clinical trial with pooled random donor platelets, collected using the buffy coat process, and two ancillary clinical trials a 20-patient clinical trial to qualify the system for its commercial configuration and a 40-patient clinical trial to extend qualification of the system to platelets collected by Baxter's apheresis collection system. A CE Mark application for marketing approval of the INTERCEPT Platelet System has been submitted. Regulatory applications for marketing approval in Australia and Canada have also been submitted. In the United States, Cerus has completed its 671-patient Phase III SPRINT clinical trial with platelets collected by Baxter's apheresis collection system. Cerus has begun the regulatory application process for approval of the INTERCEPT Platelet System in the United States.

*Pathogen Inactivation Studies.* Laboratory and non-primate animal model studies conducted by Cerus have indicated the efficacy of the INTERCEPT Platelet System for the inactivation of a broad array of viral, bacterial and parasitic pathogens transmitted through blood transfusions, including HIV, CMV, HTLV, model hepatitis viruses, 17 strains of bacteria and the parasite that causes Chagas' disease. A pre-clinical study conducted by Cerus in collaboration with the National Institutes of Health demonstrated that platelet concentrates contaminated with high levels of hepatitis B virus or hepatitis C virus, and treated with the INTERCEPT Platelet System, did not transmit the viruses to susceptible animals. Cerus has tested these pathogens at and above concentrations that it believes may be present in contaminated platelet concentrates. Similar laboratory studies have indicated inhibition of white blood cell activity, including the inhibition of synthesis of certain proteins associated with adverse immune reactions. In addition, three studies conducted by Cerus have indicated that use of the platelet pathogen inactivation system prevented graft-versus-host disease in two pre-clinical mouse models.

*Pre-Clinical Safety Studies.* Cerus has successfully completed a comprehensive series of pre-clinical safety studies for the INTERCEPT Platelet System. Completed safety studies of amotosalen and the INTERCEPT Platelet System include acute toxicology, three-month tolerability, general pharmacology, reproductive toxicology, genotoxicity, carcinogenicity, phototoxicity and absorbance, distribution, metabolism and excretion (ADME) studies. Results from each of these studies have consistently demonstrated a very strong safety profile for the INTERCEPT Platelet System.

*Clinical Trials.* In March 1996, Cerus completed a Phase Ia single-blind, randomized clinical trial in 23 healthy human subjects divided between two sites. This study used a cross-over design in which all subjects received both treated and untreated platelets. The study compared the proportion of transfused platelets circulating in the first hours after transfusion (post-transfusion recovery) and the length of time the transfused platelets circulate in the recipient's bloodstream (lifespan) of a small volume of five-day-old treated and untreated platelets. Under current FDA regulations, platelets may not be stored for more than five days after collection from the donor. This pilot study was conducted without the use of the CAD, which was evaluated in Phase IIa.

In September 1996, Cerus completed a Phase Ib single-blind, randomized, cross-over clinical trial in 10 healthy human subjects. This study compared the tolerability and safety of photochemically treated platelets processed with the CAD with untreated platelets. This second study

involved the transfusion of full therapeutic doses of platelets given at the maximum tolerable transfusion rate. No adverse events attributable to transfusion with the treated platelets were reported. Post-transfusion levels of amotosalen in plasma and clearance of amotosalen were measured. These clinical data, together with Cerus' pre-clinical data, reflected acceptable safety margins and cleared the INTERCEPT Platelet System for a Phase IIa clinical trial.



In November 1996, Cerus completed a Phase IIa clinical trial designed to measure the post-transfusion platelet recovery and lifespan of photochemically treated platelets processed with the CAD and stored for five days. This study was conducted in 16 healthy subjects from the Phase Ia study to permit comparisons with prior results. In Cerus' Phase IIa clinical study report, the average post-transfusion recovery of five-day-old platelets treated with Cerus' platelet pathogen inactivation system was lower than that of the untreated five-day-old platelets. Although this difference was statistically significant, the average post-transfusion recovery was within the range of average recoveries reported in most published studies funded by NIH and Baxter, as well as in a number of other studies reported in the scientific literature. These published studies used currently approved processing and storage systems. In addition, in Cerus' clinical study, the average lifespan of treated platelets was shorter than that of untreated platelets. Although this difference was statistically significant and the average lifespan was lower than the range of average untreated platelet lifespans reported in the published studies referred to above, the average lifespan was within the distribution of ranges of untreated platelet lifespans reported in such studies. Post-transfusion recovery and lifespan of five-day-old standard platelets varies widely, even in healthy individuals. As a result, there is no established regulatory or clinical standard for post-transfusion recovery and lifespan of platelets. The clinical investigators reported no adverse events attributable to transfusion with the treated platelets.

In July 1997, Cerus completed a Phase IIb clinical trial in 15 healthy subjects available from the Phase IIa clinical trial to assess the combined effect of treatment with the INTERCEPT Platelet System and gamma irradiation on post-transfusion platelet recovery and lifespan. The mean platelet recovery and life span data collected in Phase IIb were consistent with those of the IIa study, and fell within the range of published studies of currently approved platelet concentrates. The clinical investigators reported no adverse events attributable to transfusion with the treated platelets. Cerus believes, based on discussions with the FDA, that the post-transfusion recovery and lifespan of platelets following treatment with the INTERCEPT Platelet System are clinically acceptable.

In November 1998, Cerus completed a Phase IIc clinical trial in 42 platelet-deficient patients. The Phase IIc trial was initially designed as a double-blind, randomized, cross-over study in which double dose platelet transfusions were given to platelet-deficient patients and post-transfusion platelet count increment and bleeding time correction were measured. To increase its experience in patients prior to a Phase III trial, Cerus amended the Phase IIc protocol to include patients for whom platelet count increment, but not bleeding time correction, would be measured and to add a second site to evaluate the system with platelets collected using alternate automated collection equipment. Based on the results from this study, the FDA cleared Cerus to proceed into a Phase III clinical trial. The Phase IIc clinical trial, given its small size, was of limited statistical power.

In August 2000, Cerus completed its European Phase III EuroSPRITE clinical trial of treated pooled random donor platelets in 103 patients requiring platelet transfusions. The study was conducted in four European countries. The random donor platelets were collected using the buffy coat process, which is the predominant method used in Europe to prepare platelet concentrates. The trial was a double-blind, randomized, controlled study designed to assess the therapeutic efficacy of platelets treated with the INTERCEPT Platelet System.

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. A preliminary analysis of the EuroSPRITE data showed 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 and considered clinically acceptable. Additional statistical analysis presented at the meeting of the American Society of Hematology in December 2000 showed comparable efficacy of INTERCEPT platelets to that of control platelets and the preservation of platelet performance and function following pathogen inactivation with the INTERCEPT Platelet System.

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 patients. 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 the medical literature for untreated platelets. No serious adverse events were directly attributed to the use of the INTERCEPT Platelet System.

Cerus has completed a 20-patient clinical trial in Europe to qualify the system for its commercial configuration. Cerus also has completed a 40-patient clinical trial in Europe to extend qualification of the system to platelets collected by Baxter's apheresis collection system.

In March 2001, Cerus completed its United States Phase III SPRINT clinical trial. 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 comparison of the proportion of patients with moderate bleeding 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, achieving the trial's primary endpoint 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. Severe bleeding and duration of platelet support were not statistically different between the groups. The trial data also demonstrated that INTERCEPT platelets were associated with a statistically lower percentage of transfusion reactions than untreated platelets. Evaluation of other secondary measures of platelet count increment (measurements of post-transfusion platelet count increase) and number of platelet transfusions per patient showed a statistical difference between the INTERCEPT platelets and the untreated group, but these differences did not affect the primary trial goal of demonstrating equivalence in the proportion of patients with moderate bleeding between the two groups. Adverse events and serious adverse events were not statistically different between the groups and were consistent with expectations in the seriously ill patient population undergoing intensive chemotherapy.

The Phase III United States SPRINT trial was designed to assess the therapeutic efficacy of platelets treated with the INTERCEPT Platelet System for platelets collected by Baxter's apheresis collection system. In order to obtain FDA approval of the INTERCEPT Platelet System for use in treating pooled random donor platelets, Cerus will need to complete development of an additional configuration of its platelet system and conduct additional clinical studies. Additionally, because of the risk of bacterial growth, current FDA rules require that pooled platelets be transfused within four hours of pooling, and, as a result, most pooling occurs at hospitals. The INTERCEPT Platelet System is intended to permit storage of platelets for five days after treatment and pooling by the blood center,



which would reduce hospital costs associated with the pooling process. In order for the INTERCEPT Platelet System to be effectively implemented at blood centers for use with pooled random donor platelets, the FDA-imposed limit on the time between pooling and transfusion will need to be lengthened or eliminated for INTERCEPT platelets.

***FFP Program***

*FFP Usage and Market.* Plasma is a noncellular component of blood that contains coagulation factors and is essential for maintenance of intravascular volume. Plasma is either separated from collected units of whole blood or collected directly by apheresis. The collected plasma is then packaged and frozen to preserve the coagulation factors. The frozen plasma is then designated for use as FFP or made available for fractionation into plasma derivatives. FFP is the primary source of blood clotting factors and is used to control bleeding in patients who have clotting factor deficiencies, such as patients undergoing transplants or other extensive surgical procedures, patients with chronic liver disease or certain genetic clotting factor deficiencies, and to treat certain diseases that require plasma exchange therapy.

Cerus estimates the production of FFP in 2001 to have been 2.5 million transfusion units in North America, 2.0 million transfusion units in Western Europe and 2.3 million transfusion units in Japan. Based on a study of six blood centers conducted in October 1998 on behalf of Cerus, the estimated base price of a 250 ml transfusion unit of FFP in the United States ranges from approximately $26 to $55. In comparison, donor retest procedures have a $56 to $110 added cost per transfusion unit, and solvent detergent pathogen inactivation has been designated for reimbursement for outpatients by the Health Care Financing Administration at a rate of $169 per transfusion unit. A typical therapeutic transfusion consists of four transfusion units of FFP.

*INTERCEPT Plasma System.* The pathogen inactivation system for FFP uses the same psoralen compound and illumination device and a CAD similar to that being used with the INTERCEPT Platelet System. The INTERCEPT Plasma System is designed to be compatible with plasma collected either manually or by apheresis. In the INTERCEPT Plasma System, untreated plasma is transferred to a disposable container with amotosalen. The mixture of amotosalen and plasma is then illuminated for approximately three minutes. The treated plasma then undergoes a removal step, which uses the CAD to reduce the amount of residual amotosalen and amotosalen breakdown products, and is transferred into the final storage container and frozen in accordance with standard protocols.

*Development Status.* The INTERCEPT Plasma System currently is in Phase III clinical trials in the United States.

*Pathogen Inactivation Studies.* Laboratory studies conducted by Cerus to date have indicated the efficacy of the INTERCEPT Plasma System for the inactivation in FFP of a broad array of viral pathogens transmitted through blood transfusion. A pre-clinical study conducted by Cerus in collaboration with the National Institutes of Health demonstrated that FFP contaminated with high levels of hepatitis B virus or hepatitis C virus, and treated with the INTERCEPT Plasma System, did not transmit the viruses to susceptible animals. Cerus has conducted laboratory studies indicating the efficacy of the INTERCEPT Plasma System for the inactivation of the parasite that causes Chagas' disease. Because of the mechanism of action of the INTERCEPT Plasma System, Cerus believes that the system also inhibits white blood cell activity. Although bacterial contamination in FFP is typically not as significant a problem as in platelets, Cerus believes that the INTERCEPT Plasma System will inactivate bacteria at the levels typically found in FFP. To date, Cerus has conducted no studies to detect inhibition of white blood cell activity in FFP and limited studies on bacteria in FFP. There can be no assurance that the INTERCEPT Plasma System will effectively inactivate white blood cells or bacteria.



*Coagulation Function Studies.* Cerus has assessed the impact of amotosalen photochemical treatment on the function of plasma proteins. Plasma derived from whole blood or apheresis must be frozen within eight hours of collection to meet the standard as "fresh frozen plasma." After freezing, FFP may be stored for up to one year, thawed once and must be transfused within four hours of thawing. Cerus has performed laboratory studies measuring the coagulation function activity of various clotting factors in FFP after photochemical treatment, CAD treatment, freezing and thawing. Cerus believes that data from these laboratory studies indicate that treated FFP maintained adequate levels of coagulation function for FFP. There can be no assurance that the FDA or foreign regulatory authorities would view such levels of coagulation function as adequate.

*Pre-Clinical Safety Studies.* Cerus has successfully completed a series of pre-clinical safety studies for the INTERCEPT Plasma System. Completed safety studies include acute toxicology, three-month tolerability, general pharmacology, reproductive toxicology, genotoxicity, carcinogenicity, phototoxicity and ADME studies. Results from each of these studies have consistently demonstrated a very strong safety profile for the INTERCEPT Plasma System. Cerus believes that all pre-clinical safety studies required for regulatory approval have been completed, however, regulatory authorities may require additional pre-clinical safety studies to be performed.

*Clinical Trials.* In July 1997, Cerus completed a Phase I clinical study in healthy subjects that demonstrated the safety and tolerability of FFP treated with the INTERCEPT Plasma System as well as the comparability of post-transfusion coagulation factors between subjects transfused with treated and untreated FFP.

In November 1998, Cerus completed a Phase IIa clinical trial. In this study, 27 healthy subjects donated plasma. The Phase IIa study showed that post-transfusion coagulation factor levels of subjects receiving FFP treated with the INTERCEPT Plasma System were comparable to those of subjects receiving untreated FFP. There were no safety issues attributable to transfusion of the treated FFP.

In 1999, Cerus completed a Phase IIb clinical trial, in patients, of the INTERCEPT Plasma System. The study was a controlled, double-blind trial in 13 patients diagnosed with chronic liver diseases. Each patient, prior to an invasive surgical or diagnostic procedure, received a therapeutic dose of up to two liters of either treated or untreated FFP. Correction of patients' blood clotting time and certain coagulation factor levels after transfusion of treated FFP were recorded and compared, and found to be comparable to those of patients receiving untreated FFP. The Phase IIb clinical trial, given its small size, was of limited statistical power.

In January 2001, Cerus completed a Phase IIIa clinical trial of the INTERCEPT Plasma System. The open-label trial, which was conducted in collaboration with the National Hemophilia Foundation's Hemophilia Research Society, included 34 patients with a variety of hereditary blood clotting factor deficiencies. Patients with these deficiencies are susceptible to bleeding or increased blood clotting and may require plasma transfusions to prevent or stop bleeding. The Phase IIIa results, although not statistically powered, showed that infusions of plasma treated with the INTERCEPT Plasma System were well tolerated and resulted in an increase in blood clotting factor levels consistent with historical controls using non-pathogen inactivated plasma.

In May 2001, Cerus completed a Phase IIIb clinical trial of the INTERCEPT Plasma System. The multi-center, randomized, controlled, double-blind 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 untreated plasma. In addition, the safety and adverse events of INTERCEPT plasma compared to untreated plasma showed comparability between the two groups.

Patient enrollment is ongoing in a Phase IIIc trial. The trial is a prospective, double-blind, randomized, controlled study of treated versus untreated FFP used in therapeutic plasma exchange of 30 patients with a disease called thrombotic thrombocytopenic purpura (TTP).

***Red Blood Cell Program***

*Red Blood Cell Usage and Market.* Red blood cells are essential components of blood that carry oxygen to tissues and carbon dioxide to the lungs. Red blood cells may be transfused as a single treatment in surgical and trauma patients with active bleeding or on a repeated basis in patients with acquired anemia or genetic disorders, such as sickle cell anemia, or in connection with chemotherapy.

Cerus estimates the production of red blood cells in 2001 to have been 16 million transfusion units in North America, 17 million transfusion units in Western Europe and 4 million transfusion units in Japan. Based on a study of six blood centers conducted in October 1998 on behalf of Cerus, the estimated base cost of a transfusion unit of red blood cells in the United States ranges from approximately $66 to $93. A typical red blood cell transfusion consists of two or more red blood cell transfusion units. A red blood cell transfusion may also require one or more additional procedures with additional costs ranging from $10 to $164 for each procedure. The procedures are used to address problems presented by white blood cells and to conduct pathogen diagnostic testing beyond the standard testing.

*INTERCEPT Red Blood Cell System.* The INTERCEPT Red Blood Cell System uses a Helinx compound, S-303, which undergoes irreversible chemical reactions with DNA and RNA, as does amotosalen, but does not require light. S-303, a small molecule synthesized by Cerus, is one of a proprietary class of compounds called frangible anchor-linker-effectors (FRALEs). The selection of S-303 was based on an extensive analysis of the compound's safety and its ability to inactivate pathogens and harmful white blood cells, and red blood cell survival and function after treatment with S-303. The active S-303 compound has been designed to rapidly decompose into non-reactive byproducts following the pathogen inactivation process.

*Development Status.* The INTERCEPT Red Blood Cell System is in Phase III clinical trials in the United States.

*Pathogen Inactivation Studies.* Laboratory studies by Cerus have indicated the efficacy of the INTERCEPT Red Blood Cell System for the inactivation of a broad array of viral and bacterial pathogens with preservation of red blood cell function. Cerus has also conducted laboratory studies that have indicated inhibition of white blood cell activity. Because of the mechanism of action of the INTERCEPT Red Blood Cell System and based on studies performed with FRALEs similar to S-303, Cerus believes that the system will also inactivate protozoa in red blood cells. However, to date, Cerus has conducted no studies on protozoa with S-303 in red blood cells, and therefore cannot be certain that the INTERCEPT Red Blood Cell System would effectively inactivate protozoa. Cerus is currently conducting additional pathogen inactivation validation studies on the INTERCEPT Red Blood Cell System.

*Pre-Clinical Safety Studies.* Cerus has successfully completed a number of pre-clinical safety studies for the INTERCEPT Red Blood Cell System. Completed safety studies include acute and chronic toxicology, reproductive toxicology, general pharmacology, ADME and genotoxicity studies. The results of these studies have consistently demonstrated a strong safety profile for the INTERCEPT Red Blood Cell System. Cerus plans to complete additional pre-clinical safety studies of the INTERCEPT

Red Blood Cell System prior to seeking regulatory approval, including carcinogenicity studies. Cerus may be required by regulatory authorities to perform additional pre-clinical safety studies.

*Clinical Trials.* In May 1999, Cerus completed a Phase Ia clinical trial of the INTERCEPT Red Blood Cell System. The study was a randomized, controlled trial in 42 healthy subjects. The study was designed to evaluate the post-transfusion viability of treated red blood cells that were stored for 35 days prior to transfusion. The study showed that the circulation of treated red blood cells exceeded the American Association of Blood Banks' standard for red blood cell recovery 24 hours after transfusion.

In October 1999, Cerus completed a Phase Ib clinical trial of the INTERCEPT Red Blood Cell System. The study included 28 healthy subjects, each of whom received four transfusions of treated red blood cells. The study demonstrated that there was no detectable immune response directed against treated red blood cells that were stored for 35 days prior to transfusion. The study also showed that circulation of treated red blood cells exceeded the American Association of Blood Banks standard for red blood cell recovery in response to multiple small doses of treated red blood cells 24 hours after transfusion.

In July 2001, Cerus completed a Phase Ic clinical trial of the INTERCEPT Red Blood Cell System. The two-part trial enrolled 29 individuals in a crossover protocol under which individuals were transfused in random sequence with INTERCEPT red blood cells and conventional red blood cells that had not undergone a pathogen inactivation process. The results of this trial showed that INTERCEPT red blood cells demonstrated comparable survival to conventional red blood cells. The average post-transfusion recovery for both types of red cells exceeded the commonly accepted blood bank standard of 75 percent. In the second part of the study, 11 additional subjects received full unit transfusions of 35 day-old INTERCEPT red cells. The full unit transfusions were well tolerated.

In January 2002, Cerus initiated a Phase III clinical trial of the INTERCEPT Red Blood Cell System for acute transfusion support. The multi-center, double-blind, randomized trial is expected to enroll approximately 200 patients requiring acute red blood cell support as a result of cardiac surgery. The primary endpoint of the trial is a comparison of the clinical performance of INTERCEPT red blood cells to control red blood cells, which are not prepared with a pathogen inactivation process.

In February 2002, Cerus received FDA concurrence to proceed with its pivotal Phase III trial of the INTERCEPT Red Blood Cell System for chronic transfusion support. The multi-center, double-blind, randomized trial is expected to enroll approximately 50 patients who require red blood cell transfusion support for the treatment of chronic anemia due to hereditary disorders, such as sickle cell disease or thalassemia. In this crossover trial, each patient will receive, in random order, red blood cells treated with the INTERCEPT process and control red blood cells that are not prepared with a pathogen inactivation process. The primary endpoint of the trial is a comparison of the amount of INTERCEPT red blood cells and control red blood cells transfused to manage the patients' chronic anemia. Data from the two Phase III trials are expected to support both European CE Mark and U.S. PMA registration applications.

***ACIT Program***

Cerus believes its Helinx technology may have application in treating T-cells (white blood cells) that are transfused during stem cell (blood-forming) transplantation procedures used to treat certain cancers such as lymphoma and leukemia. Cerus has conducted pre-clinical studies that have indicated that donor T-cells treated with its technology may reduce the risk of serious complications and may also improve the availability and success rate of bone marrow transplantation.

*Stem Cell Transplantation.* Stem cells used for transplantation can be harvested from either bone marrow or circulating blood. ACIT uses donor T-cells, which are transfused to improve immune



function in patients whose immune systems have been weakened by disease or disease-related therapies such as chemotherapy and radiation therapy. Donor T-cells are typically transfused following a bone marrow or stem cell transplantation, which is used principally in leukemia and lymphoma patients to reconstitute blood-forming cells after chemotherapy or radiation therapy to kill leukemia and lymphoma cells. The stem cells are collected from the patient (autologous transplantation) or from a closely-matched donor (allogeneic transplantation). Autologous transplantation is typically safer but is not a curative therapy and often results in a relapse of the disease.

*Graft-Versus-Host Disease.* Allogeneic transplantation can be curative, but carries significant risk of complications such as GVHD and viral and bacterial infections, which often lead to the patient's death. GVHD is nearly always fatal and occurs when the donor white blood cells recognize the patient's body as foreign and proliferate and attack the patient's healthy tissue. Allogeneic transplantation also requires very close matching between the donor and the patient. Often, patients die from the progression of disease while awaiting transplantation from a matched donor.

*Stem Cell Transplantation Market.* Bone marrow and stem cell transplantation are emerging as the primary treatments for many patients diagnosed with a variety of advanced malignant diseases. Typical diseases for which this therapy is used include chronic and acute leukemias and non-Hodgkin's lymphoma where first line therapies, such as chemotherapy, have not been effective. Each year, over 200,000 new cases of these diseases are diagnosed. Cerus believes that there are potential applications for its ACIT system beyond allogeneic stem cell transplantation procedures for leukemia and lymphoma.

*Donor T-Cell Treatment System.* Cerus believes that it can apply its Helinx technology to treat donor T-cells to improve the outcomes of stem cell transplantation procedures. Cerus is developing a system designed to treat the T-cells in a way that will preserve therapeutic properties while eliminating the cells' ability to proliferate and attack the patient's healthy tissues.

*Development Status.* Cerus' ACIT program is in Phase I clinical trials in the United States.

*Pre-Clinical Studies.* Laboratory and animal studies conducted and presented by Cerus have indicated that its Helinx technology can treat T-cells to prevent proliferation while preserving the cells' ability to aid engraftment and to improve transplant outcomes. Cerus has also completed animal studies that indicate that its technology can facilitate engraftment of donor stem cells, which suggests the system has the potential to increase the number of patients eligible to receive allogeneic transplants.

*Clinical Trials.* In 2001, Cerus completed a Phase I clinical study of its ACIT system designed to treat allogeneic donor T-cells with amotosalen for use as supplemental therapy in conjunction with mismatched bone marrow transplantation for leukemia patients. The study measured the tolerability and safety of amotosalen treated allogeneic T-cells in patients who received closely matched allogeneic bone marrow transplants. The data suggest Helinx treated T-cells were well tolerated and the doses tested in this study did not result in dose-limiting acute GVHD.

Cerus is collaborating with the National Marrow Donor Program to pursue additional clinical studies of its ACIT system in bone marrow transplants from unrelated donors. Cerus cannot provide assurance as to the timing or acceptance of the design of this planned study, or any later studies.

***Future Product Development***

Cerus believes that its Helinx technology may have applications beyond inactivating pathogens in blood products and in modifying T-cells to improve clinical outcomes of cellular therapies. In addition to its plans to pursue the therapeutic potential of its Helinx technology, Cerus also plans to expand its product candidate pipeline by exploring other development areas where it can address large, unmet medical needs.



***Alliance with Baxter***

Cerus has established an alliance with Baxter for the development of the INTERCEPT Blood Systems. Under two primary development, manufacturing and marketing agreements, Cerus and Baxter generally share development activities with the primary development activity for the compounds and the pre-clinical and clinical studies by Cerus and the primary development activity for the system disposables and devices byBaxter. Upon commercialization, Cerus will provide the inactivation compounds and Baxter will be responsible for manufacturing and assembling the system disposables and illumination devices. Baxter will also be responsible for marketing, selling and distributing the systems. The programs under these agreements can be terminated by either party under certain circumstances, see "Risk Factors We rely heavily on Baxter for development funding, manufacturing, marketing and sales."

*Agreement with Baxter for the Development of the INTERCEPT Platelet System.* Cerus has a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Platelet System for inactivation of viruses, bacteria and other infectious pathogens in platelets used for transfusion. This agreement provides for Baxter and Cerus to generally share system development costs equally, subject to mutually determined budgets established from time to time, and for Cerus to receive approximately 33.5% of revenue from sales of inactivation system disposables after each party is reimbursed for its cost of goods to the extent the cost exceeds specified amounts. Baxter has an exclusive, worldwide distribution license and will be responsible for manufacturing and marketing the INTERCEPT Platelet System following regulatory approval. The agreement also provides for Baxter to make a $5 million cash milestone payment to Cerus upon approval by the FDA of an application to market products developed under the platelet program, comparable approval in Europe or termination of the program.

*Agreement with Baxter for the Development of the INTERCEPT Red Blood Cell System and INTERCEPT Plasma System.* Cerus also has a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Red Blood Cell System and the

INTERCEPT Plasma System for inactivation of viruses, bacteria and other infectious pathogens in red blood cells and FFP for transfusion. This agreement provides for Baxter and Cerus generally to share INTERCEPT Red Blood Cell System development costs equally, subject to mutually determined budgets established from time to time. Cerus is solely responsible for funding the development costs of the INTERCEPT Plasma System. Baxter has an exclusive, worldwide distribution license and will be responsible for manufacturing and marketing the INTERCEPT Red Blood Cell System and INTERCEPT Plasma System following regulatory approvals. The agreement also provides for an equal sharing of revenue from sales of INTERCEPT Red Blood Cell System disposables, and for Cerus to receive 75% and Baxter to receive 25% of revenue from sales of INTERCEPT Plasma System disposables, after each party is reimbursed for its cost of goods and a specified percentage allocation, not to exceed 14% of revenue, is retained by Baxter for marketing and administrative expenses.

From inception through December 31, 2001, Cerus has received $46.7 million in equity investments from Baxter and $25.9 million in an equity investment from Baxter International Inc. and Subsidiaries Pension Trust, and has recognized $25.0 million in revenue from Baxter.

Baxter has the ability to terminate any of the development programs under certain circumstances.

***Alliance with Kirin Brewery Co. Ltd.***

In January 2001, Cerus entered into a collaborative agreement with the Pharmaceutical Division of Kirin to develop and market products for stem cell transplantation based on Cerus' Helinx technology. Under the terms of the agreement, Cerus and Kirin will jointly develop the products. Cerus has received an initial license fee of $1 million, and may receive additional payments upon achievement of development milestones. In addition, Kirin will fund all development expenses for the Asia-Pacific



region and a portion of Cerus' development activities aimed at obtaining product approval in the United States. Upon product approval, Kirin will market the products in the Asia-Pacific region, including Japan, China, Korea and Australia, and Cerus will receive a specified share of product revenue, including a royalty and reimbursement of its cost of goods. Cerus retains all marketing rights for the rest of the world, including the United States and Europe.

***Cooperative Agreement with the Armed Forces of the United States***

In February 2001, Cerus was awarded a $3.5 million multi-year cooperative agreement by the Army Medical Research Acquisition Activity division of the Department of Defense. Cerus received the award to develop its pathogen inactivation technologies to improve the safety and availability of blood that may be used by the United States Armed Forces for medical transfusions. Under the conditions of the agreement, Cerus will conduct research on the inactivation of infectious pathogens, including unusual viruses, bacteria and parasites, which are of particular concern to the Armed Forces. Cerus, in collaboration with investigators at Walter Reed Army Institute of Research, also will investigate ways to improve the storage and shelf life of blood and blood components, which may be used for medical transfusion support in the field. Also under the terms of the agreement, Cerus would receive commercial rights to the discoveries and inventions arising from the research performed under the collaboration.

***Agreement with the Consortium for Plasma Science***

In December 1998, Cerus and the Consortium entered into an agreement for the development of a pathogen inactivation system for source plasma used for fractionation. The Consortium is co-funded by four plasma fractionation companies: Alpha Therapeutics Corporation, Aventis Behring, Bayer Corporation and Baxter. The Consortium, which is a separate entity from its members, provides research and development funding worldwide for technologies to improve the safety of source plasma. Under the agreement, the Consortium funded development of Cerus' proprietary technology for use with source plasma. Subject to the Consortium meeting certain funding requirements, Cerus will pay the Consortium a royalty based on a percentage of product sales, if any.

**Research Grants**

Cerus has an ongoing federal grant administered by the National Institutes of Health (NIH), which funds pre-clinical research related to its ACIT program. The grant is a three-year award, ending in July 2002, and totals approximately $800,000. Cerus retains all rights to technology funded by these grants, subject to certain rights of the federal government if Cerus fails to commercialize the technology in a timely manner or if action is necessary to alleviate health or safety needs not addressed by Cerus, to meet requirements for public use specified by federal regulations or in the event Cerus were to breach certain agreements. The United States government also has a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for or on its behalf any subject invention throughout the world.

**Manufacturing and Supply**

Cerus has used, and intends to continue to use, third parties to manufacture and supply the amotosalen and S-303 inactivation compounds for its systems for use in clinical trials and for the potential commercialization of its products in development. Cerus has no experience in manufacturing products for commercial purposes and does not have any manufacturing facilities. Consequently, Cerus is dependent on contract manufacturers for the production of compounds and on Baxter for other system components for development and commercial purposes.



Under its agreements with Baxter, Cerus is responsible for developing and delivering its proprietary compounds to Baxter for incorporation into the final system configuration. Baxter is responsible for manufacturing or supplying the disposable units, such as blood storage containers and related tubing, as well as any device associated with the inactivation process. This arrangement applies both to the current supply for clinical trials and, if applicable regulatory approvals are obtained, the future commercial supply.

In order to provide the inactivation compounds for the INTERCEPT Platelet System and INTERCEPT Plasma System, Cerus has contracted with one manufacturing facility for synthesis of amotosalen. Although Cerus believes that this manufacturer is capable of providing sufficient quantities of amotosalen for commercial use, based on our current expectations, no commercial production of amotosalen has been completed. Cerus currently has a stock of compound sufficient to support the anticipated remaining clinical trials planned for the INTERCEPT Platelet System and INTERCEPT Plasma System, and to support the initial launch of the INTERCEPT Platelet System in Europe, if CE Mark approval is received.

The INTERCEPT Red Blood Cell System will require the manufacture of S-303, which Cerus and its manufacturers have produced in only limited quantities for Cerus' research, pre-clinical and clinical development requirements. Cerus has contracted with a manufacturing facility to produce pilot-scale quantities of S-303 sufficient for pre-clinical and clinical studies. Cerus cannot be certain that this or any new manufacturer will be able to produce S-303 on a commercial scale or that Cerus will be able to enter into arrangements for the commercial-scale manufacture of S-303 on reasonable terms, if at all.

Cerus and its contract manufacturers purchase certain raw materials from a limited number of suppliers. While Cerus believes that there are alternative sources of supply for such materials, establishing additional or replacement suppliers for any of the raw materials, if required, may not be accomplished quickly and could involve significant additional costs. Any failure by Cerus to obtain any of the materials used to manufacture Cerus' compounds from alternative suppliers, if required, would limit Cerus' ability to manufacture its compounds.

**Marketing, Sales and Distribution**

The target market for INTERCEPT Blood Systems consists of the blood centers and hospitals that collect, store and distribute blood and blood components. In the United States, the American Red Cross collects and distributes approximately 50% of the nation's supply of blood and blood components. Other major blood centers include the New York Blood Center and United Blood Services, each of which distributes approximately 6% of the nation's supply of blood and blood components. In Western Europe and Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. Hospital-affiliated blood banks also store and dispense blood and blood components but generally do not collect significant quantities of blood. Cerus believes that, if its products receive appropriate regulatory approvals, the relatively concentrated nature of the market may facilitate its ability to penetrate the market. However, if Cerus fails to gain market acceptance from any of these participants, its business will suffer materially.

Cerus believes that market acceptance of INTERCEPT Blood Systems will depend, in part, on its ability to provide acceptable evidence of the safety, efficacy and cost-effectiveness of the systems, as well as the ability of blood centers to obtain appropriate FDA licenses and adequate reimbursement for such systems. Cerus believes that market acceptance of the INTERCEPT Blood Systems will also depend upon the extent to which physicians, patients and health care payors perceive that the benefits of using blood components treated with the systems justify the additional costs and processing requirements in a blood supply that has become safer. While Cerus believes that the INTERCEPT



Blood Systems are able to inactivate pathogens up to concentrations that Cerus believes are present in contaminated blood components when the blood is donated, Cerus cannot be certain that contamination will never exceed such levels. Cerus does not expect that the INTERCEPT Blood

Systems will be able to inactivate all known and unknown infectious pathogens, and the inability to inactivate certain pathogens may affect the market acceptance of the systems. INTERCEPT Blood Systems may not gain any significant degree of market acceptance among blood centers, physicians, patients and health care payors, even if clinical trials demonstrate safety and efficacy and necessary regulatory approvals and health care reimbursement approvals are obtained.

If appropriate regulatory approvals are received, Baxter will be responsible for the worldwide marketing, sales and distribution of the INTERCEPT Blood Systems. Cerus currently has a small marketing group that helps support Baxter's marketing organization; however, Cerus does not intend to develop its own independent marketing and sales organization and expects to continue to rely on Baxter to market and sell the INTERCEPT Blood Systems. If Baxter is not successful in marketing the INTERCEPT Blood Systems, Cerus will not receive revenue from the systems and its business will suffer.

**Competition**

Cerus believes that the INTERCEPT Blood Systems have certain competitive advantages over competing pathogen inactivation methods that are either on the market, or in development. The INTERCEPT Blood Systems are designed for use in blood centers, to integrate with current blood collection, processing and storage procedures. Competing products in development or currently on the market, such as solvent-detergent treated plasma, use centralized processing, taking the blood product away from the blood center. The INTERCEPT Blood Systems are designed for use with single units of blood products. Some potential competitors utilize a pooling process prior to pathogen inactivation, which significantly increases the risk of contamination by pathogens that are not inactivated. Additionally, the INTERCEPT Blood Systems are being developed for each of the three transfused blood components platelets, plasma and red blood cells. There are currently no competitors that have pathogen inactivation methods in clinical trials for all three of these components. In addition to competition from other pathogen inactivation methods, Cerus expects to encounter competition from other approaches to blood safety, including methods of screening blood products for pathogens.

Cerus believes that the primary competitive factors in the market for pathogen inactivation of blood products will include the breadth and effectiveness of pathogen inactivation processes, ease of use, the scope and enforceability of patent or other proprietary rights, product price, product supply and marketing and sales capability. In addition, the length of time required for products to be developed and to receive regulatory and, in some cases, reimbursement, approval is an important competitive factor. Cerus believes it competes favorably with respect to these factors, although there can be no assurance that it will be able to continue to do so. The biopharmaceutical field is characterized by rapid and significant technological changes. Accordingly, Cerus' success will depend in part on its ability to respond quickly to medical and technological changes through the development and introduction of new products. Product development involves a high degree of risk, and there can be no assurance that Cerus' product development efforts will result in any commercially successful products.

**Patents, Licenses and Proprietary Rights**

Cerus' success depends in part on its ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on the proprietary rights of Cerus. Cerus' policy is to seek to protect its proprietary position by, among other methods, filing United States and foreign patent applications related to its proprietary technology, inventions and improvements that are important to the development of its business. As of



December 31, 2001, Cerus owned 54 issued or allowed United States patents and 58 issued or allowed foreign patents. Cerus' patents expire at various dates between 2003 and 2018. In addition, Cerus has 25 pending United States patent applications and has filed 16 corresponding patent applications under the Patent Cooperation Treaty, which are currently pending in Europe, Japan, Australia and Canada, and of which six are also pending in China and Hong Kong. Proprietary rights relating to Cerus' planned and potential products will be protected from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. There can be no assurance that any patents owned by, or licensed to, Cerus will afford protection against competitors or that any pending patent applications now or hereafter filed by, or licensed to, Cerus will result in patents being issued. In addition, the laws of certain foreign countries do not protect Cerus' intellectual property rights to the same extent as do the laws of the United States.

Cerus is a licensee under a license agreement with respect to two United States patents covering inventions pertaining to psoralen-based photochemical decontamination treatment of whole blood or blood components and four United States patents relating to vaccines, as well as related foreign patents. Whether Cerus' psoralen-based pathogen inactivation systems practice either of the photochemical decontamination patents depends on an interpretation of the scope of the patent claims. If such systems practice such patents, the license would provide for Cerus to make certain milestone payments that may be credited against any royalties payable by Cerus. The license requires a royalty payable by Cerus on revenue from such systems and certain annual minimum royalty payments per year until termination of the license. The manner in which any

such milestone payments and royalties would be shared by Baxter, if at all, has not been determined. Cerus does not believe that any amounts that might be payable by it under the agreement to date would be material.

Cerus is a licensee under a license agreement with Emory University with respect to two United States patents covering inventions related to its ACIT program. The license provides for Cerus to make certain future milestone payments to Emory as well as royalties on any sales of products using the licensed technology.

**Government Regulation**

Cerus and its products are comprehensively regulated in the United States by the FDA and, in some instances, by state and local governments, and by comparable governmental authorities in other countries. The FDA regulates drugs, medical devices and biologics under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. These laws and implementing regulations govern, among other things, the development, testing, manufacturing, record keeping, storage, labeling, advertising, promotion and premarket clearance or approval of products subject to regulation.

Cerus believes the INTERCEPT Blood Systems will be regulated by the FDA as medical devices. It is also possible, however, that the FDA will decide to regulate the INTERCEPT Blood Systems as biologics, as drugs, as combination products including drugs or biologics and one or more medical devices, or as drugs or biologics with one or more medical devices (i.e., the blood bags and light source) requiring separate approval or clearance. Whether the FDA regulates the INTERCEPT Blood Systems as devices or as one or more of the other alternatives, it is likely that the FDA's Center for Biologics Evaluation and Research will be principally responsible for regulating the INTERCEPT Blood Systems.

Before a medical device may be marketed in the United States, the FDA must clear a premarket notification (a 510(k)) or approve a PMA for the product. Before a new drug may be marketed in the United States, the FDA must approve an NDA for the product. Before a biologic may be marketed in the United States, the FDA must approve a Biologic License Application (BLA). Before a combination



product can be marketed in the United States, it must have an approved PMA, NDA or BLA, depending on which statutory authority the FDA elects to use.

Despite the multiplicity of statutory and regulatory possibilities, the steps required before approval are essentially the same whether the product is ultimately regulated as a medical device, biologic, drug, a combination product or a combination thereof. The steps required before a medical device, drug or biologic may be approved for marketing in the United States pursuant to a PMA, NDA or BLA, respectively, generally include (i) pre-clinical laboratory and animal tests, (ii) submission to the FDA of an investigational device exemption (IDE) (for medical devices) or an investigational new drug application (IND) (for drugs or biologics) for human clinical testing, which must become effective before human clinical trials may begin, (iii) appropriate tests to show the product's safety, (iv) adequate and well-controlled human clinical trials to establish the product's safety and efficacy for its intended indications, (v) submission to the FDA of a PMA, NDA or BLA, as appropriate and (vi) FDA review of the PMA, NDA or BLA in order to determine, among other things, whether the product is safe and effective for its intended uses. In addition, the FDA inspects the facilities at which the product is manufactured and will not approve the product unless compliance with current Good Manufacturing Practices (cGMP) or Quality System Regulation requirements is satisfactory. The steps required before a medical device may be cleared for marketing in the United States pursuant to a 510(k) are likely to be the same, except that instead of conducting tests to demonstrate safety and efficacy, data, including clinical data if necessary, must be obtained to show that the product is substantially equivalent to a legally marketed device, and the FDA must make a determination of substantial equivalence rather than a determination that the product is safe and effective. Cerus believes the FDA will require a PMA for each of the INTERCEPT Blood Systems. Cerus' European investigational plan is based on the INTERCEPT Platelet System and INTERCEPT Plasma System being categorized as Class III drug/device combinations under the Medical Device Directives (MDD) of the European Union. However, there can be no assurance that this approach will be accepted by European authorities. The European Union requires that medical devices affix the CE Mark, an international symbol of adherence to quality assurance standards and compliance with the MDD. Failure to receive CE Mark certification will prohibit Cerus from selling its products in the European Union. Individual European countries may require additional in-country studies to support an approval to market the products in such countries.

Cerus expects to submit modular PMA applications for some of its product candidates. The content, order and submission timing of the modules must be approved by the FDA, and a modular PMA application cannot be approved until all modules have been submitted to, reviewed by and accepted by the FDA. Cerus is using a modular process for its PMA application for the INTERCEPT Platelet System, and intends to use a modular process for the PMA application for the INTERCEPT Plasma System. Cerus cannot guarantee that the FDA will approve of modular submissions for any of Cerus' future product candidates.

In addition to the regulatory requirements applicable to Cerus and its products, there are regulatory requirements applicable to Cerus' prospective customers, the blood centers that process and distribute blood and blood products. Blood centers and others will likely be required to obtain approved license supplements from the FDA before using the INTERCEPT Blood Systems. There can be no assurance that any blood centers will be able to obtain the required licenses on a timely basis, or at all.



To support Cerus' requests for regulatory approval to market the INTERCEPT Blood Systems, Cerus conducts various types of studies, including toxicology studies to evaluate product safety, laboratory and animal studies to evaluate product effectiveness and human clinical trials to evaluate the safety, tolerability and effectiveness of treated blood components. Cerus believes that, in deciding whether each of the INTERCEPT Blood Systems is safe and effective, the regulatory authorities are likely to take into account whether it adversely affects the therapeutic efficacy of blood components as compared to the therapeutic efficacy of blood components not treated with the system, and the regulatory authorities will weigh the system's safety, including potential toxicities of the inactivation compounds, and other risks against the benefits of using the system in a blood supply that has become safer. Cerus has conducted many toxicology studies designed to demonstrate the INTERCEPT Blood Systems' safety, and will be required to conduct additional studies to evaluate the safety of the S-303 compound. There can be no assurance that regulatory authorities will not require further toxicology or other studies of Cerus' products. Based on discussions with the FDA and European regulatory authorities, Cerus believes that data from human clinical studies is required to demonstrate the safety of treated blood components and their therapeutic comparability to untreated blood components, but that only data from laboratory and animal studies, not data from human clinical studies, will be required to demonstrate the system's efficacy in inactivating pathogens. In light of these criteria, Cerus' clinical trial programs for the INTERCEPT Blood Systems consist of studies that differ from typical Phase I, Phase II and Phase III clinical studies.

The Phase III SPRINT trial was conducted using prototype system disposables and ultraviolet light devices. Cerus plans to perform laboratory studies to demonstrate equivalency between the prototype and the commercial configuration. Cerus cannot be certain that these studies will be successful or the FDA will not require additional studies, which could delay commercialization. If Cerus decides to seek FDA approval of the INTERCEPT Platelet System for use in treating pooled random donor platelets, Cerus will be required to conduct additional clinical studies. In addition, there currently are three principal manufacturers of automated apheresis collection equipment, including Baxter. The equipment of each manufacturer collects platelets into plastic disposables designed for that equipment; thus, a pathogen inactivation system designed for disposables used by one manufacturer will not necessarily be compatible with other manufacturers' collection equipment. Under an agreement with Haemonetics Corporation, Baxter has agreed to provide Haemonetics with a platelet storage solution proprietary to Cerus and Baxter, with the objective that platelets collected on certain future Haemonetics apheresis collection equipment may be directly treated using the INTERCEPT Platelet System. However, Cerus intends initially to seek FDA approval of the INTERCEPT Platelet System configured for Baxter's apheresis collection equipment. If Cerus determines that compatibility with other equipment is desirable, it will need to develop additional processing procedures and system configurations. Cerus believes that the FDA will also require supplemental clinical data before approving its system for use with platelets collected using other equipment.

Cerus also is conducting its Phase III clinical trials of the INTERCEPT Plasma System and INTERCEPT Red Blood Cell System using prototype system disposables and devices. Cerus plans to perform laboratory studies to demonstrate equivalency to the commercial configurations. Cerus cannot be certain that the FDA will not require additional studies, which could delay commercialization.

**Health Care Reimbursement and Reform**

The future revenue and profitability of biopharmaceutical and related companies as well as the availability of capital to such companies may be affected by the continuing efforts of the United States and foreign governments and third-party payors to contain or reduce costs of health care through various means. In the United States, given federal and state government initiatives directed at lowering the total cost of health care, it is likely that the United States Congress and state legislatures will



continue to focus on health care reform and the cost of pharmaceuticals and on the reform of the Medicare and Medicaid systems.

Cerus' ability to commercialize its products successfully will depend in part on the extent to which appropriate reimbursement levels for the cost of the products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly challenging the prices charged for medical products and services. The trend toward managed health

care in the United States and other countries and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may all affect the prices for Cerus' products.

**Employees**

As of February 28, 2002, Cerus had 169 employees, 114 of whom were engaged in research and development and 55 in general and administrative. No employees of Cerus are covered by collective bargaining agreements, and Cerus believes that its relationship with its employees is good.



## RISK FACTORS

*Cerus' business faces significant risks. If any of the events or circumstances described in the following risks actually occurs, Cerus' business may suffer, the trading price of Cerus' common stock could decline and Cerus' financial condition or results of operations could be harmed. These risks should be read in conjunction with the other information set forth in this report.*

**Our products are in development; if our pre-clinical and clinical trials are not successful or the data are not considered sufficient by regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue.**

We have no products that have received regulatory approval for commercial sale. Our product candidates are in various stages of development, and we face the risks of failure inherent in developing medical devices and biotechnology products based on new technologies. Our products must satisfy rigorous standards of safety and efficacy before the United States Food and Drug Administration and international regulatory authorities can approve them for commercial use. Our platelet, fresh frozen plasma, red blood cell and stem cell transplantation programs are undergoing clinical testing. We must provide the FDA and foreign regulatory authorities with pre-clinical, clinical and manufacturing data that demonstrate our products are safe, effective and in compliance with federal regulations before the products can be approved for commercial sale.

We have completed our European Phase III (CE Mark) clinical trial of the INTERCEPT Platelet System with random donor platelets, which are platelets prepared from several units of whole blood pooled together in a manual process. In December 2000, we submitted a CE Mark application for marketing approval of the INTERCEPT Platelet System in Europe. We have completed a 20 patient ancillary clinical trial in Europe to qualify the system for its commercial configuration. We have also completed a 40-patient ancillary clinical trial in Europe to extend qualification of the system to platelets collected by our development and marketing partner, Baxter Healthcare Corporation's apheresis collection system, which is a system to separate and collect a full unit of platelets from a donor using an automated collection machine. We completed our Phase III clinical trial of the INTERCEPT Platelet System in the United States in March 2001, but we have not yet submitted all of the modules of our pre-market approval application with the FDA. We have completed Phase IIIa and Phase IIIb clinical trials of the INTERCEPT Plasma System in the United States and are conducting a Phase IIIc clinical trial. We have completed a Phase Ic clinical trial of the INTERCEPT Red Blood Cell System in the United States and initiated Phase III clinical trials. Our allogeneic cellular immune therapy (referred to as ACIT) program, designed to improve the outcome of bone marrow transplantation procedures through use of T-cells treated with the Helinx technology, is in Phase I clinical trials in the United States. Last, our source plasma pathogen inactivation system and Epstein-Barr Virus cellular vaccine program are in pre-clinical development. We will have to conduct significant additional research and pre-clinical (animal) and clinical (human) testing before we can file additional applications for product approval with the FDA and foreign regulatory authorities. Clinical trials in particular are expensive and have a high risk of failure. In addition, to compete effectively, our products must be easy to use, cost-effective and economical to manufacture on a commercial scale. Any of our product candidates may fail in the testing phase or may not attain market acceptance, which could prevent us from achieving profitability.

It may take us several years to complete our clinical testing, and failure can occur at any stage of testing. We cannot rely on interim results of trials to necessarily predict their final results, and acceptable results in early trials might not be repeated in later trials. Any trial may fail to produce results satisfactory to the FDA or foreign regulatory authorities. Pre-clinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical

trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to a program are successful.

**We may fail to complete our clinical trials on time or be unable to complete them at all.**

Some of our clinical trials involve patient groups with rare medical conditions, which has in the past made, and may continue to make, it difficult to identify and enroll a sufficient number of patients to complete the trials on time. Other factors, including the unavailability of blood products during times of emergency, could also delay our clinical trials. Our product development costs will increase if we have additional delays in testing or approvals. Significant clinical trial delays could allow competitors to bring products to market before we do and impair our ability to commercialize our products.

**We are using prototype components in our pre-clinical studies and clinical trials and have not completed the components' commercial design.**

The system disposables and ultraviolet light sources we use in our pre-clinical studies and clinical trials are prototypes of those to be used in the final products. As a result, we plan to perform studies, both pre-clinical and clinical, to demonstrate the equivalence of the prototype and the commercial design. However, regulatory authorities may require us to perform additional studies, both pre-clinical and clinical, using the commercial versions of the systems, which may increase our expenses and delay the commercialization of our products. If we fail to develop commercial versions of the systems on schedule, our competitors may be able to bring products to market before we do, which would delay or diminish our potential revenue.

**Because our product candidates have not been manufactured on a commercial scale, we face manufacturing uncertainties that could limit their commercialization.**

Our product candidates, including many of the components, have never been manufactured on a commercial scale. We intend to use third-party manufacturers to produce commercial quantities of the chemical compounds and other components to be used in our products to inactivate viruses, bacteria and other pathogens. These inactivation compounds and other components have never been produced in commercial quantities, and we currently do not have any third-party manufacturing agreements in place for commercial production of compounds or other components. Any commercial manufacturer will need to develop new methods and processes to manufacture these compounds on a commercial scale and demonstrate to us, the FDA and foreign regulatory authorities that its commercial scale manufacturing processes comply with government regulations. It may be difficult or impossible to economically manufacture our products on a commercial scale.

Baxter is responsible for manufacturing and assembling our pathogen inactivation systems. Baxter intends to rely on third parties to manufacture and assemble some of the system components, many of which are customized and have not been manufactured on a commercial scale. Baxter has not produced the pathogen inactivation systems in commercial quantities and may not be able to manufacture and assemble them, or do so economically. Prior to product sales of the platelet system in Europe, Baxter will need to complete studies relating to illumination device manufacturing that will enable it to make a self-declaration concerning quality of device manufacturing. In the United States, studies related to the illumination device, disposable and compound manufacturing and stability will need to be completed and included in FDA submissions before the FDA would consider the application for approval. It may be difficult or impossible to complete those studies in a timeframe consistent with intended commercialization.



**If our third-party manufacturers fail to produce our compounds and other product components satisfactorily and in sufficient quantities, we may incur delays, shortfalls and additional expenses.**

A limited number of suppliers manufacture our inactivation compounds for our use in product development, including clinical trials. Of these manufacturers, we currently have contracted with one manufacturer to provide enough amotosalen, the inactivation compound we use in our platelet and fresh frozen plasma systems, to meet our anticipated clinical trial, product development and initial platelet system European launch requirements, and we have contracted with one manufacturer to produce an intermediate compound, S-301, which is used by another manufacturer as a raw material of S-303, the inactivation compound we use in our red blood cell system. If any of these manufacturers cannot produce our compounds in the required quantities or to the required standards, we may face delays and shortfalls before we are able to identify alternate or additional manufacturers to meet these requirements. While alternative suppliers for the inactivation compounds exist, any new manufacturer will have to prove both to us and to the FDA and foreign regulatory authorities that its manufacturing process complies with government regulations. Identifying and qualifying such new suppliers could be an expensive and time-consuming process.

Baxter has advised us that it intends to purchase certain key components of the pathogen inactivation systems from a limited number of suppliers. While we believe there are alternative suppliers for these components, it would be expensive and time-consuming to establish additional or replacement suppliers for these components. If Baxter were unable to find adequate suppliers for these components, we may be required to redesign the systems, which could lead to additional testing and clinical trials. If we were required to redesign the products, our development costs would increase, and our programs could be delayed significantly.

**Our products may not achieve acceptance in, or be rapidly adopted by, the health care community.**

Even if our product candidates receive regulatory approval for commercial sale, physicians, patients and healthcare payors may not believe that the benefits of using our systems justify their additional cost, because the blood supply has become safer or for other reasons. We believe that our ability to successfully commercialize products will depend in part on the availability of adequate reimbursement for product costs and related treatment of blood components from governmental authorities and private health care insurers (including health maintenance organizations), which are increasingly attempting to contain health care costs by limiting both the extent of coverage and the reimbursement rate for new tests and treatments. In addition, our products may not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens may inhibit their acceptance. In addition, for logistical and financial reasons, the transfusion industry has not always integrated new technologies into their processes, even those with the potential to improve the safety of the blood supply. If our products fail to achieve market acceptance, we may never become profitable.

**We will need to develop and test additional configurations of our platelet pathogen inactivation system to address the entire market.**

In the United States, our efforts to develop our systems to inactivate viruses, bacteria and other pathogens in platelets have focused almost entirely on apheresis platelets collected on Baxter's automated collection platform. Apheresis platelets are platelets that are collected from a single donor using an automated collection machine. Currently, we estimate that the majority of platelets used in the United States are collected by apheresis, with the remainder prepared from pooled random donor platelets. Blood centers in the United States preparing random donor platelets may be reluctant to switch to apheresis collection, and the FDA may require us to make our systems to inactivate viruses, bacteria and other pathogens in platelets compatible with random donor platelets. In order to develop a platelet pathogen inactivation system compatible with random donor platelets, we plan to perform additional product development and testing, including clinical trials. These development activities would



increase our costs significantly, and may not be successful. In addition, FDA regulations limit the time from pooling to transfusion to four hours to minimize the proliferation of bacterial contamination in the pooled product. As a result, most pooling occurs in hospitals. Our platelet system is designed for use in blood centers, not at hospitals, and is intended to permit storage and transfusion of treated platelets for up to five days after pooling. The FDA's time limit between pooling and transfusion currently precludes the use of our system with pooled random donor platelets. Although our system is designed to reduce the risk of bacterial contamination, we cannot predict whether the FDA would remove this process time constraint to allow our system to be used with pooled random donor platelets, and we have not yet made a formal request for the FDA to do so.

Baxter is one of three primary manufacturers of equipment for the collection of apheresis platelets in the United States. The equipment, design and materials used to collect the platelets vary from manufacturer to manufacturer. We have conducted our pre-clinical and clinical studies in the United States for apheresis platelets collected using only Baxter's equipment and materials. Under an agreement with Haemonetics Corporation, Baxter has agreed to provide Haemonetics with a platelet storage solution proprietary to Cerus and Baxter, with the intent that platelets collected on certain future Haemonetics apheresis collection equipment may be directly treated using our platelet system. Baxter and we are also adapting our platelet system to allow compatibility with other manufacturers' equipment. Such adaptations will require additional product development and testing, including clinical trials. These development activities will increase our costs significantly, and may not be successful. Market acceptance of the platelet system in the United States may be delayed until the system receives regulatory approval for use on such other equipment.

In Europe, platelets also are typically prepared from several units of whole blood using a semi-automated process known as the buffy coat process. We have conducted our pre-clinical and clinical studies for platelets prepared by the buffy coat process using only Baxter's platelet collection and pooling materials. As a result, market acceptance in Europe of our platelet system for platelets prepared by the buffy coat process will depend on market acceptance of Baxter's platelet collection and pooling sets or on our ability to develop products compatible with other manufacturers' platelet collection and pooling sets.

For apheresis platelets in Europe, we have conducted a clinical trial of our pathogen inactivation system using largely Baxter's equipment and materials. Baxter and we are adapting our platelet system to allow compatibility with other manufacturers' equipment. Such adaptations will

require additional product development and testing. These development activities may not be successful. Market acceptance of the platelet system in Europe may be delayed until the system receives regulatory approval for use on such other equipment.

**If we receive regulatory approval for our products, a small number of customers will determine market acceptance of our pathogen inactivation systems.**

The market for our pathogen inactivation systems is dominated by a small number of blood collection organizations. In the United States, the American Red Cross collects and distributes approximately 50% of the nation's supply of blood and blood components. Other major United States blood collection organizations include the New York Blood Center and United Blood Services, each of which distributes approximately 6% of the nation's supply of blood and blood components. In Western Europe and Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. Even if our products receive regulatory approval to be commercialized and marketed, due to the intense market concentration, failure to properly market, price or sell our products to any of these large customers could significantly diminish potential product revenue.



**We rely heavily on Baxter for development funding, manufacturing, marketing and sales.**

We have two development and commercialization agreements with Baxter for our systems to inactivate viruses, bacteria and other pathogens in each of the three commonly transfused blood components: platelets, fresh frozen plasma and red blood cells, and we rely on Baxter for significant financial and technical contributions to these programs. Since the beginning of our relationship with Baxter in 1993 through December 31, 2001, we have received $46.7 million in equity investments from Baxter and $25.9 million from the Baxter International Inc. and Subsidiaries Pension Trust, and we have recognized $25.0 million in revenue from Baxter. Our ability to develop, manufacture and market these products successfully depends significantly on Baxter's performance under these agreements.

*We rely on Baxter for manufacturing and supplying components of our pathogen inactivation systems.* Under the terms of our agreements, Baxter is responsible for manufacturing or supplying the disposable units, such as blood storage containers and related tubing, as well as any device associated with the inactivation processes. If these agreements were terminated or if Baxter otherwise failed to deliver an adequate supply of components, we would be required to identify other third-party component manufacturers. We cannot assure you that we would be able to identify such manufacturers on a timely basis or enter into contracts with such manufacturers on reasonable terms, if at all. Any delay in the availability of devices or disposables from Baxter could delay the submission of INTERCEPT Blood Systems for regulatory approval or the market introduction and subsequent sales of such systems. Moreover, the inclusion of components manufactured by others could require us to seek new approvals from government regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals.

*We rely on Baxter for the marketing, sales and distribution of our pathogen inactivation systems*. We currently have a small marketing group that helps support Baxter's marketing organization; however, we do not intend to develop our own independent marketing and sales organization and expect to continue to rely on Baxter to market and sell the INTERCEPT Blood Systems. If our joint development agreements with Baxter are terminated or if Baxter is unable to market the products successfully, we will be required to find another marketing, sales and distribution partner or develop these capabilities ourselves. We may not be able to find a suitable partner on favorable terms or on a timely basis, if at all. Developing marketing, sales and distribution capabilities ourselves would delay commercialization of our pathogen inactivation systems and increase our costs.

*We share control over management decisions*. Baxter and we share responsibility for managing the development programs for the pathogen inactivation systems. Management decisions are made by a management board that has equal representation from both Baxter and us. Our interests and Baxter's may not always be aligned. Disagreements with Baxter may be time-consuming to resolve and cause significant delays in the development of our products. If we disagree with Baxter on program direction, a neutral party will make the decision. The neutral party may not decide in our best interest. Under the agreements, Baxter may independently develop a pathogen inactivation system for fresh frozen plasma using a pre-existing technology. Such an effort by Baxter could create conflicts in our joint program for the development of a pathogen inactivation system for fresh frozen plasma.

*Baxter can terminate our agreements or fail to perform*. Baxter can terminate the agreements without cause under certain circumstances. A development program under the agreements may be terminated by either party on 90 days' notice in the case of the platelet program, or 270 days' written notice in the case of the fresh frozen plasma or red blood cell program. If Baxter terminates the agreements or fails to provide adequate funding to support the product development efforts, we will need to obtain additional funding from other sources and will be



required to devote additional resources to the development of our products. We cannot assure you that we would be able to find a suitable substitute partner in a timely manner, on reasonable terms or at all. If we fail to find a suitable partner, our research, development or commercialization of certain planned products would be delayed significantly, which would cause us to incur additional expenditures.

**Our products are subject to extensive regulation by domestic and foreign governments.**

Our products under development and anticipated future products are subject to extensive and rigorous regulation by United States local, state and federal regulatory authorities and by foreign regulatory bodies. These regulations are wide-ranging and govern, among other things:

product development;

product testing;

product manufacturing;

product labeling;

product storage;

product premarket clearance or approval;

product sales and distribution;

product use standards and documentation; and

product advertising and promotion.

The FDA and other agencies in the United States and in foreign countries impose substantial requirements upon the manufacturing and marketing of products such as those we are developing. The process of obtaining FDA and other required regulatory approvals is long, expensive and uncertain. The time required for regulatory approvals is uncertain, and the process typically takes a number of years, depending on the type, complexity and novelty of the product. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses, or we may not be successful at all.

Even if our product candidates receive approval for commercial sale, their marketing and manufacturing will be subject to continuing FDA and other regulatory requirements, such as requirements to comply with good manufacturing practices. The failure to comply with these requirements could result in enforcement action, which could harm our business. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the product or manufacturer, including withdrawal of the product from the market. Regulatory authorities may also require post-marketing testing, which can involve significant expense. The government may impose new regulations that could further delay or preclude regulatory approval of our potential products. We cannot predict the impact of adverse governmental regulation that might arise from future legislative or administrative action.

Distribution of our products outside the United States also is subject to extensive government regulation. These regulations, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations, vary by country. In addition to CE Mark approval in Europe, we will need to obtain regulatory approvals in individual European countries to market our products. The level of additional product testing varies by country, but could take up to six months or more to complete after CE Mark approval. Failure to obtain necessary regulatory approvals or any other failure to comply with regulatory requirements could result in reduced revenue and earnings.



To support our requests for regulatory approval to market our product candidates, we have conducted and intend to conduct various types of studies including:

- toxicology studies to evaluate product safety;
- laboratory and animal studies to evaluate product effectiveness;
- human clinical trials to evaluate the safety, tolerability and effectiveness of treated blood components; and
- manufacturing and stability studies.

We have conducted many toxicology studies to demonstrate our product candidates' safety, and we plan to conduct additional toxicology studies throughout the product development process. At any time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products' safety, which could delay commercialization. We believe the FDA and other regulatory authorities are likely to weigh the potential risks of using our pathogen inactivation products against the incremental benefits, which may be less compelling in light of improved safety in the blood supply. In addition, our clinical development plan assumes that we will not be required to perform human clinical studies to demonstrate our systems' ability to inactivate pathogens. Although we have discussed this plan with the FDA and other regulatory authorities, they may find it unacceptable at any time and may require human clinical trials to demonstrate efficacy in inactivating pathogens. Trials of this type may be too large and expensive to be practical.

Regulatory agencies may limit the uses, or indications, for which any of our products is approved. For example, we believe that we will be able to claim the inactivation of particular pathogens only to the extent we have laboratory or animal data to support such claims. After regulatory approval for the initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications.

In addition to the regulatory requirements applicable to us and our products, there are regulatory requirements applicable to our prospective customers, the blood centers that process and distribute blood and blood products. Blood centers and others will likely be required to obtain approved license supplements from the FDA before using products processed with our pathogen inactivation systems. This requirement or FDA delays in approving these supplements may deter some blood centers from using our products. Blood centers that do submit supplements may face disapproval or delays in approval that could provide further delay or deter them from using our products. The regulatory impact on potential customers could slow or limit the potential sales of our products.

**We have only a limited operating history, and we expect to continue to generate losses.**

We may never achieve a profitable level of operations. To date, we have engaged primarily in research and development. Our development and general and administrative expenses have resulted in substantial losses each year since our inception, including net losses of $22.6 million in 1999, $36.0 million in 2000 and $49.4 million in 2001. As of December 31, 2001, we had an accumulated deficit of approximately $173.1 million. All of our products are in the research and development stage, and we have not received any revenue from product sales. We have received all of our revenue from our agreements with Baxter, Kirin and the Consortium for Plasma Science and from federal research grants and cooperative agreements. We will be required to conduct significant research, development, clinical testing and regulatory compliance activities for each of these products. We expect our losses to continue at least until our product candidates are commercialized and achieve significant market acceptance.

**If we fail to obtain the capital necessary to fund our future operations, we will not be able to develop product candidates in our pipeline.**

Our product development programs are capital-intensive. We expect to continue to spend substantial funds for our operations for the foreseeable future. We believe that our existing capital resources, together with anticipated payments from Baxter, the United States government and projected interest income, will support our current and planned operations for at least the next 24 months. Our cash, liquidity and capital requirements will depend on many factors, including additional research and development needs, product testing results, regulatory requirements, competitive pressures and technological advances and setbacks.

We may require substantial additional funds for our long-term product development, marketing programs and operating expenses. We do not know if we will be able to raise additional funds on acceptable terms. If we raise additional funds by issuing equity securities, our existing stockholders may experience substantial dilution.

**If our competitors develop and market products that are more effective than our product candidates, our commercial opportunity will be reduced or eliminated.**

We expect our products to encounter significant competition. Our products may compete with other approaches to blood safety and improving the outcome of stem cell transplantation currently in use, as well as with future products developed by biotechnology and pharmaceutical companies, hospital supply companies, national and regional blood centers and governmental organizations and agencies. Our success will depend in part on our ability to respond quickly to medical and technological changes through the development and introduction of new products. Product development is risky and uncertain, and we cannot assure you that we will develop our products successfully. Competitors' products or technologies may make our products obsolete or non-competitive before we are able to generate any significant revenue. Many of our competitors or potential competitors have substantially greater financial and other resources than we have. They may also have greater experience in pre-clinical testing, human clinical trials and other regulatory approval procedures. Our ability to compete successfully will depend, in part, on our ability to:

attract and retain skilled scientific personnel;

develop technologically superior products;

develop lower cost products;

obtain patent or other proprietary protection for our products and technologies;

obtain required regulatory approvals for our products;

be early entrants to the market; and

manufacture, market and sell our products, independently or through collaborations.

Several companies are developing technologies that are, or in the future may be, the basis for products that will directly compete with or reduce the market for our pathogen inactivation systems. A number of companies are specifically focusing on alternative strategies for pathogen inactivation in various blood components. Precision Pharma Services, Inc. has FDA approval to market solvent-detergent treated fresh frozen plasma in the United States. If the treatment of fresh frozen plasma by solvent-detergent becomes a widespread practice, which has not happened to date, it could impair our ability to market our fresh frozen plasma pathogen inactivation system in the United States. In Europe, several companies, including Grifols, Octapharma AG and Maco Pharma International GmbH, are developing or have developed commercial systems to treat fresh frozen plasma.

Other groups are developing synthetic blood product substitutes and products to stimulate the growth of platelets, and new methods of testing blood for specific pathogens have recently been approved by the FDA. Development of any of these technologies could impair the potential market for our products.

**We may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others.**

Our commercial success will depend, in part, on obtaining and maintaining patent protection on our products and successfully defending our products against third-party challenges. Our technology will be protected from unauthorized use by others only to the extent that it is covered by valid and enforceable patents or effectively maintained as trade secrets. As a result, our success depends in part on our ability to:

obtain patents;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

As of December 31, 2001, we owned 54 issued or allowed United States patents and 58 issued or allowed foreign patents. Our patents expire at various dates between 2003 and 2018. In addition, we have 25 pending United States patent applications and have filed 16 corresponding patent applications under the Patent Cooperation Treaty, which are currently pending in Europe, Japan, Australia and Canada, and of which six are also pending in China and Hong Kong. In addition, we are a licensee under a license agreement with respect to two United States patents covering inventions pertaining to psoralen-based photochemical decontamination treatment of whole blood or blood components and four United States patents relating to vaccines, as well as related foreign patents. We are also a licensee under a license agreement with Emory University with respect to two United States patents covering inventions related to our ACIT program. The license provides for us to make certain future milestone payments to Emory as well as royalties on any sales of products using the licensed technology. We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Others may independently develop technologies similar to ours or independently duplicate our technologies. For example, a patent has recently issued to a third-party covering methods to remove psoralen compounds from blood products. We have reviewed the patent and believe our work predates the invention disclosed in that patent. We are continuing to review that patent and will make a determination as to whether any action is necessary. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

We cannot be certain that we were the first to make the inventions covered by each of our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. We may need to license the right to use third-party patents and intellectual property to continue development and commercialization of our products. We may not be able to acquire such required licenses on acceptable terms, if at all. If we do not obtain such licenses, we may need to design around other parties' patents, or we may not be able to proceed with the development, manufacture or sale of our products.



We may face litigation to defend against claims of infringement, assert claims of infringement, enforce our patents, protect our trade secrets or know-how or determine the scope and validity of others' proprietary rights. Patent litigation is costly. In addition, we may require interference proceedings declared by the United States Patent and Trademark Office to determine the priority of inventions relating to our patent applications. Litigation or interference proceedings could be expensive and time consuming, and we could be unsuccessful in our efforts to enforce our intellectual property rights.

We may rely, in certain circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We protect our proprietary technology and processes, in part, by confidentiality agreements with employees and certain contractors. However, these agreements may be breached, we may not have adequate remedies for any breach or our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others, disputes may also arise as to the rights in related or resulting know-how and inventions.

**We may be liable if our products harm people.**

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and products. We may be liable if any of our products causes injury, illness or death. We intend to obtain product liability insurance before the commercial introduction of any product, but do not know whether we will be able to obtain and maintain such insurance on acceptable terms. Any insurance we obtain may not provide adequate coverage against potential liabilities. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products.

**We may be liable if hazardous materials used in the development of our products harm the environment, our employees or other people.**

Our research and development activities involve the controlled use of hazardous materials, including certain hazardous chemicals, radioactive materials and infectious pathogens, such as HIV and hepatitis. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with regulatory requirements, we cannot eliminate the risk of accidental contamination or injury. If an accident occurs, we could be held liable for any damages that result.

**The market price of our stock may be highly volatile.**

The market prices for our securities and those of other emerging medical device and biotechnology companies have been, and may continue to be, volatile. For example, during the period January 1, 1999 to December 31, 2001, the closing sale price of our common stock as quoted on the Nasdaq National Market fluctuated from a low of $15.44 to a high of $81.88. Announcements may have a significant impact on the market price of our common stock. Such announcements may include:

biological or medical discoveries;

technological innovations or new commercial services by us or our competitors;

developments concerning proprietary rights, including patents and litigation matters;

regulatory developments in both the United States and foreign countries;

public concern as to the safety of new technologies;

general market conditions;

comments made by analysts, including changes in analysts' estimates of our financial performance; and

quarterly fluctuations in our revenue and financial results.



The stock market has from time to time experienced extreme price and volume fluctuations, which have particularly affected the market prices for emerging biotechnology and medical device companies, and which have often been unrelated to the operating performance of such companies. These broad market fluctuations may adversely affect the market price of our common stock. In the past, following periods of volatility in the market price of a company's stock, securities class action litigation has occurred against the issuing company. Such litigation could result in substantial costs and a diversion of management's attention and resources, which could have a material adverse effect on our revenue and earnings. Any adverse determination in such litigation could also subject us to significant liabilities.

**Item 2.** ***Properties***

Cerus leases approximately 21,400 square feet for its main office facility in Concord, California. The lease of the main facility extends through July 2004 with options to renew for two additional three-year periods. Cerus also has leases for approximately 17,400 square feet and approximately 9,900 square feet at two facilities, both of which contain laboratory and office space and are located near its main building in Concord. These leases extend through June 2004, with one five-year renewal option, and January 2005, respectively. Cerus has a lease for approximately 11,300 square feet of office space in a facility located near its main building in Concord. This lease extends through August 31, 2002 with four one-year renewal options. In October 2001, Cerus entered into a lease of a 14,800 square foot building. The lease extends through November 2006. The facility is currently being modified to accommodate laboratories, and Cerus intends to occupy the building in 2002. Cerus believes that its current facilities and available additional space will be adequate for the foreseeable future.

**Item 3.** ***Legal Proceedings***

None.

**Item 4.** ***Submission of Matters to a Vote of Security Holders***

None.

**PART II**

**Item 5.** ***Market for the Registrant's Common Equity and Related Stockholder Matters***

Cerus' common stock is traded on the Nasdaq National Market under the symbol "CERS." The following table sets forth, for the periods indicated, the high and low sales prices for the common stock as reported by the Nasdaq National Market:

| | High | Low |
|---|---|---|
| Year Ended December 31, 2000: | | |
| First Quarter | $ 78.50 | $ 24.63 |
| Second Quarter | 55.44 | 25.00 |
| Third Quarter | 64.50 | 42.50 |
| Fourth Quarter | 81.88 | 42.75 |
| Year Ended December 31, 2001: | | |
| First Quarter | 76.56 | 31.69 |
| Second Quarter | 76.00 | 32.25 |
| Third Quarter | 75.80 | 41.64 |
| Fourth Quarter | 57.41 | 39.55 |

On February 28, 2002, the last reported sale price of Cerus' common stock on the Nasdaq National Market was $57.94 per share. On February 28, 2002, Cerus had approximately 168 holders of record of common stock.

Cerus has not paid dividends on its common stock and does not intend to pay cash dividends on its common stock in the foreseeable future.



**Item 6.** ***Selected Financial Data***

The following table summarizes certain selected financial data for the five years ended December 31, 2001. The information presented should be read in conjunction with the financial statements and notes included elsewhere herein. The selected financial data for the periods prior to the financial statements included herein are derived from audited financial statements.

**Years Ended December 31,**

| | 2001 | 2000 | 1999 | 1998 | 1997 |
|---|---|---|---|---|---|
| | (in thousands, except per share data) | | | | |
| **Statement of Operations Data:** | | | | | |
| Revenue | $ 4,535 | $ 1,851 | $ 2,408 | $ 2,903 | $ 6,851 |
| Operating expenses: | | | | | |
| Research and development | 48,247 | 34,823 | 22,514 | 29,783 | 19,569 |
| General and administrative | 10,166 | 7,160 | 4,837 | 3,841 | 3,163 |
| Total operating expenses | 58,413 | 41,983 | 27,351 | 33,624 | 22,732 |
| Loss from operations | (53,878) | (40,132) | (24,943) | (30,721) | (15,881) |
| Net interest income | 4,611 | 4,099 | 2,315 | 1,163 | 1,217 |
| Loss before income taxes | (49,267) | (36,033) | (22,628) | (29,558) | (14,664) |
| Provision for income taxes | (100) | | | | |
| Net loss | $ (49,367) | $ (36,033) | $ (22,628) | $ (29,558) | $ (14,664) |
| Net loss per share-basic and diluted(1) | $ (3.27) | $ (2.75) | $ (2.04) | $ (3.17) | $ (1.76) |
| Shares used in computing net loss per share-basic and diluted(1) | 15,105 | 13,086 | 11,102 | 9,325 | 8,352 |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2001 | 2000 | 1999 | 1998 | 1997 |
| | (in thousands) | | | | |
| **Balance Sheet Data:** | | | | | |
| Cash, cash equivalents and short-term investments | $ 123,461 | $ 90,260 | $ 40,419 | $ 19,802 | $ 21,581 |
| Working capital | 108,606 | 78,884 | 31,951 | 537 | 21,374 |
| Total assets | 128,260 | 94,161 | 41,780 | 20,934 | 27,315 |
| Capital lease obligations, less current portion | 51 | 84 | 115 | 12 | 43 |
| Redeemable convertible preferred stock | 5,000 | 5,000 | 5,000 | 5,000 | |
| Accumulated deficit | (173,095) | (123,728) | (87,518) | (64,428) | (34,870) |
| Total stockholders' equity (deficit) | 106,755 | 76,921 | 27,959 | (3,656) | 22,475 |

(1) See Note 1 of Notes to Financial Statements for a description of the method used in computing the net loss per share.



**Item 7.** ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

*The following discussion of the financial condition and results of operations of Cerus should be read in conjunction with the Financial Statements and related Notes included elsewhere in this report. This report contains forward-looking statements that involve risks and uncertainties. Results for the periods presented are not necessarily indicative of future results.*

**Overview**

Since its inception in 1991, Cerus has devoted substantially all of its efforts and resources to the research, development and clinical testing of medical systems based on its Helinx technology. Cerus has been unprofitable since inception and, as of December 31, 2001, had an accumulated deficit of approximately $173.1 million. All of Cerus' product candidates are in the research and development stage, and Cerus has not received any revenue from product sales. Cerus must conduct significant research, development, pre-clinical and clinical evaluation and regulatory compliance activities on these product candidates that, together with anticipated general and administrative expenses, are expected to result in substantial losses at least until after commercialization. Cerus' ability to achieve a profitable level of operations in the future will depend on its ability to successfully complete development, obtain regulatory approvals and achieve market acceptance of the INTERCEPT Blood Systems. Cerus may never achieve a profitable level of operations. Further, under the agreements discussed below, a significant portion of development funding for the INTERCEPT Blood Systems is provided by Baxter based on an annual budgeting process. There can be no assurance that these agreements will not be modified or terminated.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements:

Revenue and research and development expenses Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the project are incurred. Revenue related to at risk milestones specified under development contracts is recognized as the milestones are achieved. License fees and payments for achieved milestones are non-refundable and are not subject to future performance. Cerus receives certain United States government grants that support its research effort in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred.

Investments Cerus considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist principally of short-term money market instruments and commercial paper. Cerus has classified all debt securities as available-for-sale at the time of purchase and reevaluates such designation as of each balance sheet date. The cost of securities sold is based on the specific identification method.

*Agreement with Baxter for the Development of the INTERCEPT Platelet System.* Cerus has a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Platelet System for inactivation of viruses, bacteria and other infectious pathogens in platelets used for transfusion. This agreement provides for Baxter and Cerus to generally share system development costs equally, subject to mutually determined budgets established from time to time, and for Cerus to receive approximately 33.5% of revenue from sales of inactivation system disposables after each party is reimbursed for its cost of goods to the extent the cost exceeds specific amounts. Baxter has an exclusive, worldwide distribution license and will be responsible for manufacturing and marketing the INTERCEPT Platelet System following regulatory approval. The agreement also provides for Baxter to make a $5 million cash milestone payment to Cerus upon approval by the FDA of an application to market products developed under the platelet program, comparable approval in Europe or termination of the program.



*Agreement with Baxter for the Development of the INTERCEPT Red Blood Cell System and INTERCEPT Plasma System.* Cerus also has a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Red Blood Cell System and the INTERCEPT Plasma System for inactivation of viruses, bacteria and other infectious pathogens in red blood cells and fresh frozen plasma, or FFP, for transfusion. This agreement provides for Baxter and Cerus generally to share INTERCEPT Red Blood Cell System development costs equally, subject to mutually determined budgets established from time to time. Cerus is solely responsible for funding the development costs of the INTERCEPT Plasma System. Baxter has an exclusive, worldwide distribution license and will be responsible for manufacturing and marketing the INTERCEPT Red Blood Cell System and INTERCEPT Plasma System following regulatory approvals. The agreement also provides for an equal sharing of revenue from sales of INTERCEPT Red Blood Cell System disposables, and for Cerus to receive 75% and Baxter to receive 25% of revenue from sales of INTERCEPT Plasma System disposables, after each party is reimbursed for its cost of goods and a specified percentage allocation, not to exceed 14% of revenue, is retained by Baxter for marketing and administrative expenses.

From inception through December 31, 2001, Cerus has received $46.7 million in equity investments from Baxter and $25.9 million in an equity investment from Baxter International Inc. and Subsidiaries Pension Trust, and has recognized $25.0 million in revenue from Baxter. Development funding is in the form of balancing payments made by Baxter to Cerus, if necessary, to reimburse Cerus for development spending in excess of the levels determined by Baxter and Cerus. Development funding revenue is recognized as the related project costs are incurred.

*Agreement with Kirin.* In January 2001, Cerus entered into a collaborative agreement with the Pharmaceutical Division of Kirin to develop and market products for stem cell transplantation based on Cerus' Helinx technology. Under the terms of the agreement, Cerus and Kirin will jointly develop the products. Cerus has received an initial license fee of $1 million, and may receive additional payments upon achievement of development milestones. In addition, Kirin will fund all development expenses for the Asia-Pacific region and a portion of Cerus' development activities aimed at obtaining product approval in the United States. Upon product approval, Kirin will market the products in the Asia-Pacific region, including Japan, China, Korea and Australia, and Cerus will receive a specified share of product revenue, including a royalty and reimbursement of its cost of goods. Cerus retains all marketing rights for the rest of the world, including the United States and Europe.

*Cooperative Agreement with the Armed Forces of the United States.* In February 2001, Cerus was awarded a $3.5 million cooperative agreement by the Army Medical Research Acquisition Activity division of the Department of Defense. Cerus received the award to develop its pathogen inactivation technologies to improve the safety and availability of blood that may be used by the United States Armed Forces for medical transfusions. Under the conditions of the agreement, Cerus will conduct research on the inactivation of infectious pathogens, including unusual viruses, bacteria and parasites, which are of particular concern to the Armed Forces. Cerus, in collaboration with investigators at Walter Reed Army Institute of Research, also will investigate ways to improve the storage and shelf life of blood and blood components, which may be used for medical transfusion support in combat zones. Also under the terms of the agreement, Cerus would receive commercial rights to the discoveries and inventions arising from the research performed under the collaboration.

*Agreement with the Consortium for Plasma Science.* In December 1998, Cerus and the Consortium entered into an agreement for the development of a pathogen inactivation system for source plasma used for fractionation. The Consortium is co-funded by four plasma fractionation companies: Alpha Therapeutics Corporation, Aventis Behring, Bayer Corporation and Baxter. The Consortium, which is a separate entity from its members, provides research and development funding worldwide for technologies to improve the safety of source plasma. Under the agreement, the Consortium has funded development of Cerus' proprietary technology for use with source plasma. Cerus does not expect to



receive additional funding from the Consortium. Subject to the Consortium meeting certain funding requirements, Cerus will pay the Consortium a royalty based on a percentage of product sales, if any.

**Results of Operations**

***2001 Compared with 2000***

*Revenue.* For the year ended December 31, 2001, development revenue from Baxter and the Consortium, which are related parties of Cerus, increased 29% to $2.1 million from $1.6 million for 2000. The increase was primarily from increased development revenue from Baxter for the INTERCEPT Red Blood Cell System as a result of increased expenses incurred by Cerus for pre-clinical safety studies, compound manufacturing and clinical trials in 2001. Revenue earned under the agreements with Baxter is dependent on the relative spending by Cerus and Baxter on the programs for which development costs are shared. Development funding from Baxter was 41% of total revenue for 2001. Development funding from the Consortium was 5% of total revenue for the year ended December 31, 2001.

Development funding from other sources, which includes Kirin, was $1.0 million for 2001. Development funding from Kirin was 20% of total revenue for 2001.

Revenue from government grants and cooperative agreements increased 557% to $1.4 million for 2001 from $0.2 million for 2000. The increase was principally due to revenue recognized from a cooperative agreement with the Armed Forces of the United States entered into in February 2001. Cerus also has recognized revenue under a grant from the National Institutes of Health that expires in July 2002. There can be no assurance that Cerus will receive additional government grants in the future.

Cerus anticipates that its sources of revenue until product sales occur will be limited to payments under collaboration agreements, including Cerus' development agreements with Baxter, and payments from the United States government under cooperative agreement and research grant programs. If CE Mark approval for the INTERCEPT Platelet System is received, Cerus would not expect to recognize revenue from product sales until mid-2002 or later, and would not expect significant revenue from product sales in 2002.

*Research and Development Expenses.* Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, pre-clinical safety studies, compound manufacturing and other laboratory studies. Research and development expenses increased 39% to $48.2 million for 2001 from $34.8 million for 2000. The increase was

due primarily to the addition of scientific personnel and consultants, increased development spending at Baxter and increased costs for pre-clinical safety studies and compound manufacturing. Cerus' total research and development costs incurred included $40.5 million for the INTERCEPT Blood Systems program and $7.8 million for all other programs for 2001, and $30.8 million for the INTERCEPT Blood Systems program and $4.1 million for all other programs for 2000. Cerus anticipates that its research and development expenses will continue to increase as additional filings for regulatory approval are prepared and final product configuration and testing are completed for the INTERCEPT Platelet System and INTERCEPT Plasma System, Phase III clinical trials of the INTERCEPT Red Blood Cell System continue and research and development activity relating to its other pre-clinical programs increases. Due to the inherent uncertainties and risks associated with developing biomedical products, including but not limited to intense and changing government regulation, uncertainty of future pre-clinical and clinical study results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the cost to complete these research and development projects. Cerus faces numerous risks and uncertainties associated with the successful completion of its research and development projects; see "Risk Factors" beginning on page 26.



*General and Administrative Expenses.* General and administrative expenses increased 42% to $10.2 million for 2001 from $7.2 million for 2000. The increase was principally attributable to the addition of administrative personnel and increased facilities expenses associated with expansion of Cerus' operations. Cerus expects its general and administrative expenses to continue to increase as development activities expand.

*Net Interest Income.* Net interest income increased 12% to $4.6 million for 2001 from $4.1 million for 2000. The increase was attributable primarily to increased average cash and investments balances from proceeds of the private placements of common stock to institutional investors in August 2000 and May 2001, net of reduced yields on investments due to declining interest rates. Cerus typically maintains substantial balances of cash equivalents and short-term investments to fund future research and development activities. Cerus expects to earn interest at market rates in proportion to the balances it maintains.

***2000 Compared with 1999***

*Revenue.* For the year ended December 31, 2000, development revenue from Baxter and the Consortium decreased 4% to $1.6 million from $1.7 million for 1999. Revenue earned under the agreements with Baxter is dependent on the relative spending by Cerus and Baxter on the programs for which development costs are shared. The decrease in development funding was primarily a result of reduced spending by Cerus on the source plasma program in 2000.

Government grant revenue decreased 69% to $0.2 million for 2000, compared to $0.7 million for 1999. The decrease was principally due to the expiration of certain government grants in 1999.

*Research and Development Expenses.* Research and development expenses increased 55% to $34.8 million for 2000 from $22.5 million for 1999. The increase was primarily due to the addition of scientific personnel, increased costs for clinical trials and contract research and increased expenses incurred for fee-for-service development activities at Baxter relating to the FFP program. Cerus' total research and development costs incurred included $30.8 million for the INTERCEPT Blood Systems program and $4.1 million for all other programs for 2000, and $19.1 million for the INTERCEPT Blood Systems program and $3.4 million for all other programs for 1999.

*General and Administrative Expenses.* General and administrative expenses increased 48% to $7.2 million for 2000 from $4.8 million for 1999. The increase was primarily attributable to the addition of administrative personnel associated with the expansion of Cerus' operations and increased outside consultant expenses.

*Net Interest Income.* Net interest income increased 77% to $4.1 million for 2000 from $2.3 million for 1999. The increase was attributable primarily to increased average cash and investment balances related to proceeds from the private placement of common stock to accredited investors, including Baxter, in February 2000 and the private placement of common stock to an institutional investor in August 2000.

**Liquidity and Capital Resources**

Cerus' sources of capital to date have consisted of public offerings and private placements of equity securities, payments received under its agreements with Baxter, Kirin and the Consortium, United States government grants and cooperative agreements and interest income. To date, Cerus has not received any revenue from product sales, and it will not derive revenue from product sales unless and until one or more products under development receives regulatory approval and achieves market acceptance. Cerus does not expect to receive regulatory approval for the INTERCEPT Platelet System in Europe until mid-2002 or later or in the United States until the end of 2002 or later. Cerus does not expect to receive regulatory approval for the INTERCEPT Plasma System in Europe and in the United

States until mid-2003 or later. Cerus does not expect to receive regulatory approval for the INTERCEPT Red Blood Cell System until 2004 or later.

In February 2000, Cerus completed a private placement of 1,000,000 shares of common stock at $25.00 per share and received net proceeds of $23.9 million, after deducting related expenses. The shares were purchased by institutional and other accredited investors, including Baxter, which purchased 390,000 shares.

In August 2000, Cerus completed a private placement of 1,200,000 shares of common stock at $50.00 per share and received net proceeds of $59.8 million, after deducting related expenses. The shares were purchased by an institutional investor.

In May 2001, Cerus completed two private placements of an aggregate of 1,500,000 shares of common stock at $52.00 per share and received net proceeds of $75.2 million, after deducting related expenses. Baxter International Inc. and Subsidiaries Pension Trust purchased 500,000 shares and another institutional investor purchased 1,000,000 shares.

At December 31, 2001, Cerus had cash, cash equivalents and short-term investments of $123.5 million. Net cash used in operating activities was $44.0 million in 2001, compared to $32.0 million in 2000. The use of cash primarily resulted from a net loss of $49.4 million offset by changes in other operating balances. Net cash used in investing activities in 2001 of approximately $41.8 million resulted principally from the purchases of $78.9 million of short-term investments and the purchase of $1.2 million of furniture and equipment, offset by the sales and maturities of $38.3 million of short-term investments. Working capital increased to $108.6 million at December 31, 2001 from $78.9 million at December 31, 2000, primarily due to increased cash, cash equivalents and short-term investments balances from financing activities.

Cerus believes that its available cash balances, together with anticipated cash flows from existing development and grant arrangements, will be sufficient to meet its capital requirements for at least the next 24 months. These near-term capital requirements are dependent on various factors, including the development progress and costs of the INTERCEPT Blood Systems and other programs; payments by Baxter and the United States government; and costs related to creating, maintaining and defending Cerus' intellectual property position. Cerus' long-term capital requirements will be dependent on these factors and on Cerus' ability to raise capital through public or private equity or debt financings or through additional collaborative arrangements or government grants, the achievement of milestones, regulatory approval and successful commercialization of the INTERCEPT Blood Systems and other product candidates under development, competitive developments and regulatory factors. If Baxter were to terminate its agreements with Cerus, Cerus might not be able to meet its long-term capital requirements. Future capital funding transactions may result in dilution to investors in Cerus, and may not be available on favorable terms, if at all. In August 2001, Cerus filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission to offer and sell up to $300 million of common stock and/or debt securities. Cerus has no current commitments to offer or sell securities pursuant to this registration statement.



**Commitments**

Our commitments as of December 31, 2001 were as follows:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 year | 1-3 years | 4-5 years | After 5 years |
| | (in thousands) | | | | |
| **Contractual obligations:** | | | | | |
| Capital lease obligations | $ 98 | $ 39 | $ 59 | $ | $ |
| Operating leases | 2,807 | 994 | 1,672 | 141 | |
| Total contractual cash obligations | $ 2,905 | $ 1,033 | $ 1,731 | $ 141 | $ |

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | | | | | |

**Item 7A.** ***Quantitative and Qualitative Disclosures About Market Risk***

Cerus maintains an investment portfolio of various issuers, types and maturities. These securities are generally classified as available-for-sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of stockholders' equity, if material. Unrealized gains and losses at December 31, 2001 and 2000 were not material. Cerus' investments primarily consist of short-term money market mutual funds, United States government obligations and commercial paper. Of Cerus' investments balance of $123.5 million at December 31, 2001, approximately 52% have original maturity dates of less than 90 days, 29% have original maturities of 90 days to one year and the remaining balance have maturities of two years or less. Cerus does not believe its exposure to interest rate risk to be material given the short-term nature of its investment portfolio.

**Item 8.** ***Financial Statements and Supplemental Data***

The Company's financial statements, together with related notes and report of Ernst & Young LLP, independent auditors, are listed in Item 14(a) and included herein beginning on page 47.

**Item 9.** ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

**PART III**

**Item 10.** ***Directors and Executive Officers of the Registrant***

Information regarding Cerus' directors and officers, and the compliance of certain reporting persons with Section 16(a) of the Securities Exchange Act of 1934 will be set forth under the captions "Election of Directors," "Management" and "Compliance with the Reporting Requirements of Section 16(a)" in the Company's proxy statement for use in connection with the annual meeting of stockholders to be held on June 5, 2002 (the "Proxy Statement") and is incorporated herein by reference. Cerus intends to file the Proxy Statement with the Securities and Exchange Commission within 120 days after the end of Cerus' 2001 fiscal year.

**Item 11.** ***Executive Compensation***

The information required by this item is incorporated herein by reference from the information set forth under the caption "Executive Compensation" in the Proxy Statement.



**Item 12.** ***Security Ownership of Certain Beneficial Owners and Management***

The information required by this item is incorporated herein by reference from the information set forth under the caption "Security Ownership of Certain Beneficial Owners and Management" in the Proxy Statement.

**Item 13.** ***Certain Relationships and Related Transactions***

The information required by this item is incorporated herein by reference from the information set forth under the option "Certain Transactions" in the Proxy Statement.

## PART IV

**Item 14.** ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

The following documents are being filed as part of this report on Form 10-K:

(a)

*Financial Statements.*



Other information is omitted because it is either presented elsewhere, is inapplicable or is immaterial as defined in the instructions.

(b)

No reports on Form 8-K were filed during the quarter ended December 31, 2001.

(c)

*Exhibits*

| Exhibit Number | Description of Exhibit |
|---|---|
| 3.1.1(4) | Restated Certificate of Incorporation of Cerus Corporation, as amended to date. |
| 3.2(1) | Bylaws of Cerus. |
| 4.2(1) | Specimen Stock Certificate. |
| 10.1(1) | Form of Indemnity Agreement entered into between Cerus and each of its directors and executive officers. |
| 10.2(1)* | 1996 Equity Incentive Plan. |
| 10.3(1)* | Form of Incentive Stock Option Agreement under the 1996 Equity Incentive Plan. |
| 10.4(1)* | Form of Nonstatutory Stock Option Agreement under the 1996 Equity Incentive Plan. |
| 10.5(1)* | 1996 Employee Stock Purchase Plan Offering. |
| 10.14(1) | Series E Preferred Stock Purchase Agreement, dated April 1, 1996, between Cerus and Baxter Healthcare Corporation. |
| 10.15(1) | Common Stock Purchase Agreement, dated September 3, 1996 between Cerus and Baxter Healthcare Corporation. |
| 10.16(1) | Amended and Restated Investors' Rights Agreement, dated April 1, 1996, among Cerus and certain investors. |



| | |
|---|---|
| 10.17 (9) | Development, Manufacturing and Marketing Agreement, dated December 10, 1993 between Cerus and Baxter Healthcare Corporation. |
| 10.21(1) | Industrial Real Estate Lease, dated October 1, 1992, between Cerus and Shamrock Development Company, as amended on May 16, 1994 and December 21, 1995. |
| 10.22(1) | Real Property Lease, dated August 8, 1996, between the Registrant and S.P. Cuff. |

| | |
|---|---|
| 10.23(1) | Lease, dated February 1, 1996, between Cerus and Holmgren Partners. |
| 10.24(1) | First Amendment to Common Stock Purchase Agreement, dated December 9, 1996, between Cerus and Baxter Healthcare Corporation. |
| 10.25 (1) | Amendment, dated as of January 3, 1997, to the Agreement filed as Exhibit 10.17. |
| 10.26(1) | Memorandum of Agreement, dated as of January 3, 1997, between Cerus and Baxter Healthcare Corporation. |
| 10.27 | License Agreement, dated as of November 30, 1992, by and among the Company, Miles Inc. and Diamond Scientific Corporation. |
| 10.28 (2) | Amendment to Development, Manufacturing and Marketing Agreement, dated as of March 6, 1998, by and between Cerus and Baxter Healthcare Corporation. |
| 10.29(3) | Series A Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation. |
| 10.30(3) | Series B Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation. |
| 10.31(3) | Memorandum of Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation. |
| 10.32(9) | Second Amendment to Development, Manufacturing and Marketing Agreement, dated as of June 30, 1998, by and between Cerus and Corporation. |
| 10.33 (3) | Development, Manufacturing and Marketing Agreement, dated April 1, 1996, by and between Cerus and Baxter Healthcare Baxter Healthcare Corporation, as amended and restated June 30, 1998. |
| 10.34(4) | Stockholder Rights Plan, dated November 3, 1999. |
| 10.35(5)* | 1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999 |
| 10.36(6)* | Employment Agreement with Howard G. Ervin. |
| 10.37 (7) | Collaborative License Agreement between Cerus and Kirin Brewery Company, Limited. |
| 10.38(8) | Amendment to Section 4.2 of the June 30, 1998 Development Agreement between Cerus and Baxter. |



| | |
|---|---|
| 10.39 | Lease, dated December 17, 1999 between Cerus and Redwoods Office Center, L.P. |
| 10.40 | Lease, dated October 12, 2001 between Cerus and California Development, Inc. |
| 23.1 | Consent of Ernst & Young LLP, Independent Auditors. |
| 24.1 | Power of Attorney (see signature page). |

Certain portions of this exhibit are subject to a confidential treatment order.

*

Compensatory Plan.

(1)

Incorporated by reference to Cerus' Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.

(2)

Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 1998.

(3)

Incorporated by reference to Cerus' Current Report on Form 8-K, dated June 30, 1998.

(4)

Incorporated by reference to Cerus' Current Report on Form 8-K, dated November 3, 1999.

(5)

Incorporated by reference to Cerus' Registration Statement on Form S-8, dated August 4, 1999.

(6)

Incorporated by reference to Cerus' Annual Report on Form 10-K, for the year ended December 31, 2000.

(7)

Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.

(8)

Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(9)

Incorporated by reference to Cerus' Current Report on Form 8-K, dated August 28, 2001.



**REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS**

The Board of Directors and Stockholders
Cerus Corporation

We have audited the accompanying balance sheets of Cerus Corporation as of December 31, 2001 and 2000, and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cerus Corporation at December 31, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Walnut Creek, California
January 24, 2002



**CERUS CORPORATION**

**BALANCE SHEETS**

**(in thousands, except share and per share data)**

| | December 31, | |
|---|---|---|
| | **2001** | **2000** |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 64,503 | $ 71,871 |
| Short-term investments | 58,958 | 18,389 |
| Accounts receivable from a related party | 26 | 267 |

| | December 31, | |
|---|---|---|
| Other current assets | 1,573 | 512 |
| Total current assets | 125,060 | 91,039 |
| Furniture and equipment at cost: | | |
| Laboratory and office equipment | 3,951 | 3,278 |
| Leasehold improvements | 3,665 | 3,242 |
| | 7,616 | 6,520 |
| Less accumulated depreciation and amortization | 4,604 | 3,526 |
| Net furniture and equipment | 3,012 | 2,994 |
| Other assets | 188 | 128 |
| Total assets | $ 128,260 | $ 94,161 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable to a related party | $ 5,029 | $ 1,791 |
| Accounts payable | 3,220 | 4,279 |
| Accrued compensation and related expenses | 2,634 | 1,961 |
| Accrued contract research expenses | 2,796 | 2,341 |
| Other accrued expenses | 1,817 | 1,753 |
| Deferred revenue | 927 | |
| Current portion of capital lease obligations | 31 | 31 |
| Total current liabilities | 16,454 | 12,156 |
| Capital lease obligations, less current portion | 51 | 84 |
| Commitments and contingencies | | |
| Redeemable convertible preferred stock, $.001 par value; 5,000,000 shares authorized: issuable in series; 5,000 shares issued and outstanding at December 31, 2001 and 2000; aggregate liquidation preference of $5,000 at December 31, 2001 and 2000 | 5,000 | 5,000 |
| Stockholders' equity: | | |
| Preferred stock: issuable in series; 3,327 shares issued and outstanding at December 31, 2001 and 2000; aggregate liquidation preference of $9,496 at December 31, 2001 and 2000 | 9,496 | 9,496 |
| Common stock, $.001 par value; 50,000,000 shares authorized: 15,737,165 and 14,051,762 shares issued and outstanding at December 31, 2001 and 2000, respectively | 16 | 14 |
| Additional paid-in capital | 270,338 | 191,139 |
| Accumulated deficit | (173,095) | (123,728) |
| Total stockholders' equity | 106,755 | 76,921 |
| Total liabilities and stockholders' equity | $ 128,260 | $ 94,161 |

See accompanying notes.

**CERUS CORPORATION**

**STATEMENTS OF OPERATIONS**

**(in thousands, except share and per share data)**

| | Years ended December 31, | | |
|---|---|---|---|
| | **2001** | **2000** | **1999** |
| Revenue: | | | |
| Development funding, related parties | $ 2,103 | $ 1,632 | $ 1,693 |
| Development funding, other | 993 | | |
| Government grants and cooperative agreements | 1,439 | 219 | 715 |
| Total revenue | 4,535 | 1,851 | 2,408 |
| Operating expenses: | | | |
| Research and development | 48,247 | 34,823 | 22,514 |
| General and administrative | 10,166 | 7,160 | 4,837 |
| Total operating expenses | 58,413 | 41,983 | 27,351 |
| Loss from operations | (53,878) | (40,132) | (24,943) |
| Interest income (expense): | | | |
| Interest income | 4,626 | 4,124 | 2,336 |
| Interest expense | (15) | (25) | (21) |
| Net interest income | 4,611 | 4,099 | 2,315 |
| Loss before income taxes | (49,267) | (36,033) | (22,628) |
| Provision for income taxes | (100) | | |
| Net loss | $ (49,367) | $ (36,033) | $ (22,628) |
| Net loss per share basic and diluted | $ (3.27) | $ (2.75) | $ (2.04) |
| Shares used in computing net loss per share basic and diluted | 15,105,003 | 13,086,401 | 11,102,226 |

See accompanying notes.



**CERUS CORPORATION**
**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**
**(in thousands, except share data)**

| | Preferred Stock | | Common Stock | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Shares** | **Amount** | **Shares** | **Amount** | **Additional Paid-in Capital** | **Deferred Compensation** | **Accumulated Deficit** | **Total Stockholders' Equity (Deficit)** |
| Balances at December 31, 1998 | | $ | 9,416,843 | $ 9 | $ 60,813 | $ (50) | $ (64,428) | $ (3,656) |
| Issuance of common stock | | | 62,912 | | 2,000 | | | 2,000 |

| | Preferred Stock | | Common Stock | | | | | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|---|
| Public offering of common stock, net of expenses of $3,524 | | | | 3 | 42,674 | | | 42,677 |
| Issuance of Series B preferred stock | 3,327 | 9,496 | 2,200,000 | | | | | 9,496 |
| Issuance of common stock under stock option and employee stock purchase plans and warrant exercises | | | 78,770 | | 500 | | | 500 |
| Common shares reacquired | | | (14,433) | | (10) | | | (10) |
| Accretion of cash dividend on preferred stock | | | | | | | (463) | (463) |
| Amortization of deferred compensation | | | | | | 43 | | 43 |
| Net loss | | | | | | | (22,628) | (22,628) |
| Balances at December 31, 1999 | 3,327 | 9,496 | 11,744,092 | 12 | 105,977 | (7) | (87,519) | 27,959 |
| Issuance of common stock, net of expenses of $1,314 | | | 2,200,000 | 2 | 83,683 | | | 83,685 |
| Issuance of common stock under stock option and employee stock purchase plans | | | 108,589 | | 1,479 | | | 1,479 |
| Common shares reacquired | | | (919) | | | | | |
| Accretion of cash dividend on preferred stock | | | | | | | (176) | (176) |
| Amortization of deferred compensation | | | | | | 7 | | 7 |
| Net loss | | | | | | | (36,033) | (36,033) |
| Balances at December 31, 2000 | 3,327 | 9,496 | 14,051,762 | 14 | 191,139 | | (123,728) | 76,921 |
| Issuance of common stock, net of expenses of $2,812 | | | 1,500,000 | 2 | 75,186 | | | 75,188 |
| Issuance of common stock for services | | | 11,665 | | 756 | | | 756 |
| Issuance of common stock under stock option and employee stock purchase plans | | | 173,738 | | 3,257 | | | 3,257 |
| Net loss | | | | | | | (49,367) | (49,367) |
| Balances at December 31, 2001 | 3,327 | $ 9,496 | 15,737,165 | $ 16 | $ 270,338 | $ | $ (173,095) | $ 106,755 |

See accompanying notes.



**CERUS CORPORATION**

**STATEMENTS OF CASH FLOWS**

**(in thousands)**

| | Years ended December 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| **Operating activities** | | | |
| Net loss | $ (49,367) | $ (36,033) | $ (22,628) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 1,193 | 627 | 568 |
| Issuance of common stock for services | 756 | | |
| Amortization of deferred compensation | | 7 | 43 |
| Accrued cash dividend on preferred stock, payable to a related party | | (176) | (463) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable from a related party | 241 | (267) | |

| | Years ended December 31, | | |
|---|---|---|---|
| Other current assets | (1,061) | (274) | 74 |
| Other assets | (60) | (4) | (29) |
| Accounts payable to a related party | 3,238 | 1,260 | (12,188) |
| Accounts payable | (1,059) | 2,799 | 144 |
| Accrued compensation and related expenses | 673 | 830 | 149 |
| Accrued contract research expenses | 455 | (816) | 586 |
| Accrued cash dividend on preferred stock, payable to a related party | | 176 | 463 |
| Other accrued expenses | 64 | (160) | (26) |
| Deferred revenue | 927 | | |
| Net cash used in operating activities | (44,000) | (32,031) | (33,307) |
| **Investing activities** | | | |
| Purchases of furniture and equipment | (1,236) | (2,622) | (700) |
| Proceeds from sale of equipment | 25 | | |
| Purchases of short-term investments | (78,892) | (18,657) | (71,865) |
| Sale of short-term investments | 11,000 | 2,500 | 4,115 |
| Maturities of short-term investments | 27,323 | 34,650 | 44,509 |
| Net cash provided by (used in) investing activities | (41,780) | 15,871 | (23,941) |
| **Financing activities** | | | |
| Net proceeds from sale of preferred stock | | | 9,496 |
| Net proceeds from issuance of common stock | 78,445 | 85,164 | 45,177 |
| Repurchase of common stock | | | (10) |
| Payment of cash dividend on preferred stock | | (639) | |
| Payments on capital lease obligations | (33) | (31) | (39) |
| Net cash provided by financing activities | 78,412 | 84,494 | 54,624 |
| Net increase (decrease) in cash and cash equivalents | (7,368) | 68,334 | (2,624) |
| Cash and cash equivalents, beginning of period | 71,871 | 3,537 | 6,161 |
| Cash and cash equivalents, end of period | $ 64,503 | $ 71,871 | $ 3,537 |
| Supplemental disclosures: | | | |
| Interest paid | $ 15 | $ 25 | $ 21 |
| Supplemental schedule of non-cash investing and financing activities: | | | |
| Capital lease obligations incurred | $ | $ | $ 142 |

See accompanying notes.



**CERUS CORPORATION**

**NOTES TO FINANCIAL STATEMENTS**

**December 31, 2001**

**1. The Company and Its Significant Accounting Policies**

**Basis of Presentation**

Cerus Corporation (the "Company") (formerly Steritech, Inc.), incorporated on September 19, 1991, is developing medical systems and therapeutics based on its proprietary technology for controlling biological replication. The Company's most advanced programs are focused on systems to inactivate viruses, bacteria, other pathogens and white blood cells in platelets, fresh frozen plasma ("FFP") and red blood cells intended for transfusion. The Company also is pursuing therapeutic applications of its technology to treat and prevent serious diseases. The Company has collaboration agreements with Baxter Healthcare Corporation ("Baxter"), the Pharmaceutical Division of Kirin Brewery Co., Ltd. ("Kirin") and the Consortium for Plasma Science ("the Consortium") (see Note 2). The Company has not received any revenue from product sales, and all revenue recognized by the Company to date has resulted from the Company's agreements with Baxter, Kirin and the Consortium and federal research grants and collaborative agreements. The Company will be required to conduct significant research, development, testing and regulatory compliance activities on its pathogen inactivation systems that, together with anticipated general and administrative expenses, are expected to result in substantial additional losses, and the Company may need to adjust its operating plans and programs based on the availability of cash resources. The Company's ability to achieve a profitable level of operations will depend on successfully completing development, obtaining regulatory approvals and achieving market acceptance of its pathogen inactivation systems. There can be no assurance that the Company will ever achieve a profitable level of operations.

**Use of Estimates**

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, which are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions. We record accrued liabilities for certain contract research activities, including clinical trials, pre-clinical safety studies, external laboratory studies and development activities performed by Baxter, for research and development services performed. Some of those accrued liabilities are based on estimates because billings for these activities may not occur on a timely basis consistent with the performance of the services.

**Revenue and Research and Development Expenses**

Development funding is in the form of payments made (i) by Baxter to the Company to reimburse the Company for development spending in excess of the levels determined by Baxter and the Company and (ii) by Kirin and the Consortium to reimburse the Company for certain fee-for-service development activities. Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the project are incurred. Revenue related to at risk milestones specified under development contracts is recognized as the milestones are achieved. License fees and payments for achieved milestones are non-refundable and are not subject to future performance. There was no revenue related to license fees, milestones or other up-front payments in the years ended December 31, 2001, 2000 and 1999.



In accordance with Statement of Financial Accounting Standards No. 2, "Accounting for Research and Development Expenses," research and development costs are charged to expense when incurred. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, pre-clinical safety studies, compound manufacturing and other laboratory studies. The Company's use of estimates in recording accrued liabilities for research and development activities (described previously in this Note under the heading "Use of Estimates") affects the amounts of research and development expenses and development funding revenue recorded from Baxter. Actual results may differ from those estimates under different assumptions or conditions.

The Company receives certain United States government grants that support the Company's research effort in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). SAB 101 provides guidance on the recognition, presentation and disclosure of revenue in financial statements. Any changes in revenue recognition policies resulting from SAB 101 were required to be reported as a change in accounting principle in the quarter ended December 31, 2000. The effect of adopting SAB 101 did not have a material affect on the financial statements.

**Cash, Cash Equivalents and Short-Term Investments**

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist principally of short-term money market instruments and commercial paper.

In accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities," the Company has classified all debt securities as available-for-sale at the time of purchase and reevaluates such designation as of each balance sheet date. The available-for-sale securities recorded at amounts that approximate fair value at December 31, 2001 and 2000 totaled $123,461,000 and $90,260,000, respectively.

Unrealized gains and losses at December 31, 2001 and 2000 and realized gains and losses for the years then ended were not material. Accordingly, the Company has not made a provision for such amounts in its balance sheets. The cost of securities sold is based on the specific identification method. Substantially all of the Company's cash, cash equivalents and short-term investments are maintained by three major financial institutions.

**Furniture and Equipment**

Furniture and equipment is recorded at cost less accumulated depreciation. Depreciation on furniture and equipment is calculated on a straight-line basis over the estimated useful lives of the assets (generally three to five years). Leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or the estimated useful lives of the improvements.

**Stock-Based Compensation**

The Company accounts for employee stock options in accordance with Accounting Principles Board Opinion No. 25 and has adopted the "disclosure only" alternative described in Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("FAS 123").



In April 2000, the Financial Accounting Standards Board (the "FASB") issued Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation: An Interpretation of APB No. 25" ("FIN 44"). The Company has adopted the provisions of FIN 44. The adoption of these provisions did not materially impact the Company's results of operations.

**Income Taxes**

The Company accounts for income taxes based upon Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" ("FAS 109"). Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

**Net Loss Per Share  Basic and Diluted**

The Company calculates basic and diluted earnings per share in accordance with Statement of Financial Accounting Standards No. 128, "Earnings Per Share" ("FAS 128"). Under FAS 128, basic earnings per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the assumed conversion of all dilutive securities, such as options, warrants, convertible debt and convertible preferred stock. Common stock equivalent shares from redeemable convertible preferred stock and from stock options and warrants are not included as the effect is anti-dilutive.

**Comprehensive Income (Loss)**

Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income," requires that all items that are required to be recognized under accounting standards as comprehensive income (revenues, expenses, gains and losses) be reported in a financial statement that is displayed with the same prominence as other financial statements. The Company does not have material components of other comprehensive income. Therefore, comprehensive loss is equal to net loss reported for all periods presented.

**Disclosures About Segments of an Enterprise**

Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information," establishes standards for the way public business enterprises report information about operating segments in annual financial statements. The Company has one reportable operating segment under this statement, which is the development of biomedical systems to treat blood products, and the required disclosures are reflected in the financial statements.

**New Accounting Pronouncements**

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("FAS 144"). FAS 144 is required to adopted effective January 1, 2002. FAS 144 supersedes Statement of Financial Accounting Standards No. 121, "Accounting for Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of," and provides a single accounting model for long-lived assets to be disposed. The Company does not expect the adoption of FAS 144 to have a material effect on its results of operations and financial position.



**2. Development Agreements**

**Agreements with Baxter, a Related Party of the Company**

The Company has a development and commercialization agreement with Baxter for the joint development of a system for inactivation of viruses, bacteria and other infectious pathogens in platelets used for transfusion. This agreement provides for Baxter and the Company to generally share system development costs equally, subject to mutually determined budgets established from time to time, and for the Company to receive approximately 33.5% of revenue from sales of inactivation system disposables after each party is reimbursed for its cost of goods to the extent the cost exceeds specific amounts. Baxter has an exclusive, worldwide distribution license and will be responsible for manufacturing and marketing the system following regulatory approval. The agreement also provides for Baxter to make a $5 million cash milestone payment to the Company upon approval by the FDA of an application to market products developed under the platelet program, comparable approval in Europe or termination of the program.

The Company also has a development and commercialization agreement with Baxter for the joint development of the systems for inactivation of viruses, bacteria and other infectious pathogens in red blood cells and FFP for transfusion. This agreement provides for Baxter and the Company generally to share red blood cell system development costs equally, subject to mutually determined budgets established from time to time. The Company is solely responsible for funding the development costs of the system for FFP. Baxter has an exclusive, worldwide distribution license and will be responsible for manufacturing and marketing the systems following regulatory approvals. The agreement also provides for an equal sharing of revenue from sales of red blood cell system disposables, and for the Company to receive 75% and Baxter to receive 25% of revenue from sales of FFP system disposables, after each party is reimbursed for its cost of goods and a specified percentage allocation, not to exceed 14% of revenue, is retained by Baxter for marketing and administrative expenses.

This agreement also provided that Baxter and its affiliates would not acquire capital stock of the Company if the acquisition would result in Baxter and its affiliates owning 20.1% or more of the outstanding voting power of the Company. On June 28, 2001, the Company and Baxter amended this provision to reduce the ownership limit from 20.1% to 5.4% of the outstanding voting power of the Company. The provision excludes the conversion of preferred stock and will not apply in the event a third party makes a tender offer for a majority of the outstanding voting shares of the Company, the Board of Directors decides to liquidate or sell to a third party substantially all of the Company's assets or a majority of the Company's voting securities approve a merger in which the Company's stockholders do not own a majority of the voting securities of the post-merger company. As of December 31, 2001, Baxter owned 270,337 common shares, representing approximately 1.7% of the Company's outstanding common stock.

As of December 31, 2001, the Company has received $46.7 million in equity investments from Baxter and $25.9 million in an equity investment from Baxter International Inc. and Subsidiaries Pension Trust, and has recognized approximately $25.0 million in revenue from Baxter, since inception. Development funding is in the form of balancing payments made by Baxter to the Company, if necessary, to reimburse the Company for development spending in excess of the levels determined by Baxter and the Company.

**Agreement with Kirin Brewery Co. Ltd.**

In January 2001, the Company entered into a collaborative agreement with Kirin to develop and market products for stem cell transplantation based on the Company's proprietary technology. Under the terms of the agreement, the Company and Kirin will jointly develop the products. The Company has received an initial license fee of $1 million, and may receive additional payments upon achievement of development milestones. The license fee is being deferred and recognized as development funding

ratably over the term of the agreement. In addition, Kirin will fund all development expenses for the Asia-Pacific region and a portion of the Company's development activities aimed at obtaining product approval in the United States. Upon product approval, Kirin will market the products in the Asia-Pacific region, including Japan, China, Korea and Australia, and the Company will receive a specified share of product revenue. The Company retains all marketing rights in the rest of the world, including the United States and Europe. The Company recognized $914,000 in development funding from Kirin during the year ended December 31, 2001.

**Cooperative Agreement with the Armed Forces of the United States**

In February 2001, the Company was awarded a $3.5 million cooperative agreement by the Army Medical Research Acquisition Activity division of the Department of Defense. The Company received the award to develop its pathogen inactivation technologies to improve the safety and availability of blood that may be used by the United States Armed Forces for medical transfusions. Under the terms of the agreement, the Company would receive commercial rights to any discoveries and inventions that may arise from the research performed under the collaboration.

**Agreement with the Consortium for Plasma Science**

In December 1998, the Company and the Consortium entered into an agreement for the development of a pathogen inactivation system for source plasma used for fractionation. The Consortium is co-funded by four plasma fractionation companies, one of which is Baxter, a related party of the Company. The Consortium, which is a separate entity from its members, provides research and development funding worldwide for technologies to improve the safety of source plasma. Under the agreement, the Consortium has funded development of the Company's proprietary technology for use with source plasma. Subject to the Consortium meeting certain funding requirements, the Company will pay the Consortium a royalty based on a percentage of product sales, if any. The Company recognized $226,000 and $679,000 in development funding from the Consortium during the years ended December 31, 2001 and 2000, respectively.

**3. Investments**

Available-for-sale securities are recorded at amounts that approximate fair market value. Realized and unrealized gains and losses at December 31, 2001 and 2000 were not material. Investments classified as available-for-sale were as follows:

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| | (in thousands) | |
| Money market mutual funds | $ 51,419 | $ 53,429 |
| United States and state government obligations | 31,688 | 7,147 |
| Commercial paper | 40,354 | 29,684 |
| Total investments | 123,461 | 90,260 |
| Less: amounts classified as cash equivalents | (64,503) | (71,871) |
| Short-term investments | $ 58,958 | $ 18,389 |

Of the Company's debt securities at December 31, 2001, securities in the aggregate amount of $13,084,000 have original maturity dates of less than three months, securities in the aggregate amount of $35,714,000 have original maturities of three months to one year and securities in the aggregate amount of $23,244,000 have maturities of one to two years.



**4. Commitments and Contingencies**

The Company leases its office facilities and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require the Company to pay operating costs, property taxes, insurance and maintenance. These facility leases generally contain renewal options and provisions adjusting the lease payments.

Capital lease obligations represent the present value of future rental payments under capital lease agreements for laboratory and office equipment. The original cost and accumulated amortization on the equipment under capital leases was $173,000 and $141,000, respectively, at December 31, 2001 and $173,000 and $94,000, respectively, at December 31, 2000.

Future minimum payments under capital and operating leases are as follows:

| Year ending December 31, | Capital Leases | Operating Leases |
|---|---|---|
| | (in thousands) | |
| 2002 | $ 39 | $ 994 |
| 2003 | 39 | 890 |
| 2004 | 20 | 606 |
| 2005 | | 176 |
| 2006 | | 141 |
| Total minimum lease payments | 98 | $ 2,807 |
| Amount representing interest | 16 | |
| Present value of net minimum lease payments | 82 | |
| Current portion | 31 | |
| Long-term portion | $ 51 | |

Rent expense for office facilities and certain equipment was $900,000, $592,000 and $521,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

**Patent Licenses**

The Company is a licensee under a license agreement with an unaffiliated company with respect to two United States patents covering inventions pertaining to psoralen-based photochemical decontamination treatment of whole blood or blood components and four United States patents relating to vaccines, as well as related foreign patents. Whether the Company's psoralen-based pathogen inactivation systems practice either of the photochemical decontamination patents depends on an interpretation of the scope of the patent claims. If such systems practice such patents, the license would provide for the Company to make certain milestone payments, which may be credited against any royalties payable by the Company. The license requires a royalty payable by the Company on revenues from such systems and certain annual minimum royalty payments per year until termination of the license. The manner in which any such milestone payments and royalties would be shared by Baxter, if at all, has not been determined. The Company does not believe that any amounts that might be payable by it under the agreement to date would be material.



**5. Preferred Stock**

**Series A Redeemable Convertible Preferred Stock**

Baxter holds 5,000 shares of the Company's Series A preferred stock. The holder of Series A preferred stock has no voting rights, except with respect to the approval of certain mergers, consolidations or other transactions in which the Company is not the surviving entity or becomes no longer publicly traded, or except as required by Delaware law. The holders of a majority of outstanding shares of Series A preferred stock can require the Company to redeem all of the Series A preferred stock for $1,000.00 per share if the agreement to develop the platelet system is terminated. The Company may redeem all or a portion of these shares at $1,000.00 per share, the original issuance price, either upon regulatory approval of the Company's platelet system in the United States or Europe or upon the termination of development of the platelet system. If the

shares are not redeemed upon this event, each share will be automatically converted into common shares equal to $1,000.00 divided by 120% of the average closing price of the common stock for the 30 trading days prior to system approval or 100% of the average closing price for the 15 trading days prior to and after the termination of system development. For illustrative purposes, if the Series A preferred stock were converted to common stock as if regulatory approval of the platelet system was received on December 31, 2001, 90,623 common shares would be issued, which represents 0.6% of the outstanding common shares of the Company at December 31, 2001.

**Series B Preferred Stock**

Baxter holds 3,327 shares of the Company's Series B preferred stock. The holder of Series B preferred stock has no voting rights, except with respect to the authorization of any class or series of stock having preference or priority over the Series B preferred stock as to voting, liquidation or conversion or with respect to the determination of fair market value of non-publicly traded shares received by the holder of Series B stock in the event of a liquidation, or except as required by Delaware law. At any time, the holder may convert each share of Series B preferred stock into 100 common shares. If all shares of Series B preferred stock were converted to common stock, 332,700 shares would be issued, which represents 2.1% of the outstanding common shares of the Company at December 31, 2001. The Company has the right to redeem the Series B preferred stock prior to conversion for a payment of $9.5 million.

**6. Stockholders' Equity**

**Common Stock**

In April 1999, the Company completed a public offering of 2,200,000 newly issued shares of its common stock at $21.00 per share. The Company received net proceeds of $42.7 million, after deducting offering expenses. Also in April 1999, the Company sold 62,912 shares of common stock to Baxter pursuant to the achievement of a milestone. The purchase price was $31.79 per share, for an aggregate purchase price of $2.0 million.

In November 1999, the Company's Board of Directors adopted a stockholder rights plan, commonly referred to as a "poison pill," that is intended to deter hostile or coercive attempts to acquire the Company. The stockholder rights plan enables stockholders to acquire shares of the Company's common stock, or the common stock of an acquiror, at a substantial discount to the public market price should any person or group acquire more than 15% of the Company's common stock without the approval of the Board of Directors under certain circumstances. Baxter will be exempt from the rights plan, unless it and its pension plan acquire beneficial ownership in aggregate of 20.1% or more of the Company's common stock, excluding shares of the Company's common stock issuable upon conversion of Series A or Series B preferred stock currently held by Baxter. The Company has



designated 250,000 shares of Series C Junior Participating preferred stock for issuance in connection with the stockholder rights plan.

In February 2000, the Company completed a private placement of 1,000,000 shares of common stock to accredited investors, including Baxter, which purchased 390,000 shares. The purchase price was $25.00 per share, and the Company received net proceeds of $23.9 million, after deducting related expenses.

In August 2000, the Company completed a private placement of 1,200,000 shares of common stock to an institutional investor. The purchase price was $50.00 per share, and the Company received net proceeds of $59.8 million, after deducting related expenses.

In May 2001, the Company completed private placements of an aggregate of 1,500,000 shares of common stock at $52.00 per share, and received net proceeds of $75.2 million, after deducting related expenses. Baxter International Inc. and Subsidiaries Pension Trust purchased 500,000 shares and another institutional investor purchased 1,000,000 shares.

**Stock Option Plans**

The Company has reserved 1,470,000 shares of common stock for issuance under its 1996 Equity Incentive Plan (the "1996 Plan"). The 1996 Plan provides for grants of Incentive Stock Options ("ISOs") to employees and Nonstatutory Stock Options ("NSOs"), restricted stock purchase awards, stock appreciation rights and stock bonuses to employees, directors and consultants of the Company. The ISOs may be granted at a price per share not less than the fair market value at the date of grant. The NSOs may be granted at a price per share not less than 85% of the fair market value at the date of grant. The option term is ten years. Vesting, as determined by the Board of Directors, generally occurs ratably over four years. In the event option holders cease to be employed by the Company, except in the event of death or disability or as otherwise provided in the option grant, all unvested options are forfeited and all vested options must be exercised within a three-month period, otherwise

the options are forfeited.

The Company has reserved 240,000 shares of common stock for issuance under its 1998 Non-Officer Stock Option Plan. Under the terms of this plan, options may be granted to employees or consultants at an exercise price of at least 85% of the fair market value per share at the date of grant. The option term is ten years.

The Company has reserved 3,080,000 shares of common stock for issuance under its 1999 Equity Incentive Plan (the "1999 Plan"). The 1999 Plan provides for grants of ISOs to employees and NSOs, stock bonuses and restricted stock purchase awards to employees, directors and consultants of the Company. The option term is ten years.

**Stock-Based Compensation**

The Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related interpretations in accounting for its employee stock awards because, as discussed below, the alternative fair value accounting provided for under FAS 123 requires the use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, because the exercise price of the Company's employee common stock options equals the market price of the underlying common stock on the grant date (for certain Company common stock grants), no compensation expense is recorded.

Pro forma information regarding net loss and net loss per share is required by FAS 123, and has been determined as if the Company had accounted for its employee stock options and employee stock purchase plan under the fair value method of that Statement. The fair value for these options and



shares was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions for the years ended December 31:

| | Stock Option Plans | | | Employee Stock Purchase Plan | | |
|---|---|---|---|---|---|---|
| | 2001 | 2000 | 1999 | 2001 | 2000 | 1999 |
| Expected volatility | .6837 | .8564 | .6500 | .6837 | .8564 | .6500 |
| Risk-free interest rate | 3.50% | 4.80% | 6.55% | 3.50% | 4.50% | 5.76% |
| Expected life of the option (years) | 5 | 5 | 5 | 0.5 | 0.5 | 0.5 |

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options and purchased shares have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock awards.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the awards' vesting period. The effects of applying FAS 123 on pro forma net loss are not likely to be representative of the effects on reported net loss/income for future years. The Company's reported and pro forma information for the years ended December 31 follows:

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| | (in thousands, except per share data) | | |
| Net loss, as reported | $ (49,367) | $ (36,033) | $ (22,628) |
| Net loss, pro forma | (61,606) | (43,440) | (25,103) |
| Net loss per share basic and diluted, as reported | (3.27) | (2.75) | (2.04) |
| Net loss per share basic and diluted, pro forma | (4.08) | (3.32) | (2.25) |

Activity under the stock option plans is set forth below:

| | Number of Options Outstanding | Weighted Average Exercise Price per Share |
|---|---|---|
| Balances at December 31, 1998 | 918,434 | $ 10.778 |
| Granted | 381,450 | 22.256 |
| Cancelled | (190,075) | 12.978 |
| Exercised | (43,033) | 4.943 |
| Balances at December 31, 1999 | 1,066,776 | $ 14.725 |
| Granted | 752,525 | 33.415 |
| Cancelled | (56,889) | 21.669 |
| Exercised | (95,013) | 11.943 |
| Balances at December 31, 2000 | 1,667,399 | $ 23.101 |
| Granted | 715,195 | 44.953 |
| Cancelled | (39,625) | 24.792 |
| Exercised | (161,258) | 16.711 |
| Balances at December 31, 2001 | 2,181,711 | $ 30.686 |



The weighted average fair value of options granted during the years ended December 31, 2001, 2000 and 1999 was $21.824, $19.761, and $11.039 per share, respectively. At December 31, 2001, options to purchase 1,734,303 shares of common stock were available for future grant.

| | Options Outstanding | | | Options Vested | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Number of Shares | Weighted Average Remaining Contractual Life (Years) | Weighted Average Exercise Price | Number of Shares | Weighted Average Exercise Price |
| $0.544 2.721 | 167,398 | 4.29 | $ 2.639 | 167,280 | $ 2.639 |
| $8.163 15.500 | 316,346 | 6.78 | $ 15.234 | 247,070 | $ 15.169 |
| $16.250 22.750 | 198,607 | 7.39 | $ 19.672 | 121,217 | $ 19.559 |
| $22.938 24.875 | 382,639 | 7.98 | $ 24.852 | 181,142 | $ 24.841 |
| $25.375 29.250 | 156,448 | 7.74 | $ 27.200 | 98,140 | $ 27.145 |
| $32.688 38.188 | 494,165 | 9.19 | $ 37.903 | 95,179 | $ 37.782 |
| $39.063 57.550 | 278,133 | 8.96 | $ 46.791 | 61,492 | $ 46.365 |
| $57.750 75.250 | 188,050 | 9.09 | $ 65.275 | 69,557 | $ 69.351 |
| | 2,181,786 | 7.95 | $ 30.687 | 1,041,077 | $ 24.500 |

**Employee Stock Purchase Plan**

The Company has reserved 220,500 shares of common stock for issuance under its Employee Stock Purchase Plan (the "Purchase Plan"). The Purchase Plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. Under the Purchase Plan, the Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings following the adoption of the Purchase Plan. The offering period for any offering will be no more than 27 months. Employees purchased 12,480, 12,953 and 18,784 shares under the Purchase Plan during the years ended December 31, 2001, 2000 and 1999, respectively. At December 31, 2001, 123,264 shares were available for issuance. The weighted average fair value of the rights granted during the years ended December 31, 2001, 2000 and 1999 using the Black-Scholes model was $10.636, $10.260 and $4.330, respectively.

**7. Income Taxes**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| | (in thousands) | |
| Net operating loss carryforward | $ 60,100 | $ 40,900 |
| Research and development credit carryforward | 10,900 | 8,400 |
| Certain expenses not currently deductible for tax purposes | 3,800 | 4,200 |
| Accrued liabilities | 2,000 | 1,600 |
| Capitalized research and development | 400 | 500 |
| Other | 800 | 700 |
| Gross deferred tax assets | 78,000 | 56,300 |
| Valuation allowance | (78,000) | (56,300) |
| Net deferred tax assets | $ | $ |

The valuation allowance increased by $21,700,000 and $17,200,000 for the years ended December 31, 2001 and 2000, respectively. The increase is primarily attributable to the increase in the



net operating loss and tax credit carryforwards. The Company believes that, based on a number of factors, the available objective evidence creates sufficient uncertainty regarding the realizability of the deferred tax assets such that a full valuation allowance has been recorded. These factors include the Company's history of net losses since its inception, the need for regulatory approval of the Company's products prior to commercialization, expected near-term future losses and the absence of taxable income in prior carryback years. The valuation allowance at December 31, 2001 includes $2,500,000 related to deferred tax assets arising from tax benefits associated with stock option plans. This benefit, when realized, will be recorded as an increase in stockholders' equity rather than as a reduction in the income tax provision. For the year ended December 31, 2001, the Company recorded a tax provision of $100,000, which consist of foreign withholding taxes on license fees received.

Although management's operating plans assume, beyond the near-term, taxable and operating income in future periods, management evaluation of all available information in assessing the realizability of the deferred tax assets in accordance with FAS 109, indicates that such plans were subject to considerable uncertainty. Therefore, the valuation allowance was increased to fully reserve the Company's deferred tax assets. The Company will continue to assess the realizability of the deferred tax assets based on actual and forecasted operating results.

At December 31, 2001, the Company had net operating loss carryforwards of approximately $150,900,000 for federal and $147,400,000 for state income tax purposes. The Company also had research and development tax credit carryforwards of approximately $9,500,000 for federal income tax purposes and approximately $6,200,000 for state income tax purposes at December 31, 2001. The federal net operating loss and tax credit carryforwards expire between the years 2007 and 2021. The state net operating loss carryforwards expire between the years 2002 and 2011.

Utilization of the Company's net operating losses and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code. The annual limitation may result in the expiration of net operating losses and credits before utilization.

**8. Retirement Plan**

The Company maintains a defined contribution savings plan (the "401(k) Plan") that qualifies under the provisions of Section 401(k) of the Internal Revenue Code and covers all employees of the Company. Under the terms of the 401(k) Plan, employees may contribute varying amounts of their annual compensation. The Company may contribute a discretionary percentage of qualified individual employee's salaries, as defined, to the 401(k) Plan. The Company did not contribute to the 401(k) Plan in the years ended December 31, 2001, 2000 and 1999.

**9. Quarterly Financial Information (Unaudited)**

| | Three Months Ended | | | |
|---|---|---|---|---|
| | March 31, 2001 | June 30, 2001 | September 30, 2001 | December 31, 2001 |
| | (In thousands, except per share data) | | | |
| Revenue: | | | | |
| Development funding, related parties | $ 845 | $ 1,021 | $ 69 | $ 168 |
| Development funding, other | 226 | 224 | 231 | 312 |
| Government grants and cooperative agreements | 373 | 314 | 217 | 535 |
| Total revenue | 1,444 | 1,559 | 517 | 1,015 |
| Operating expenses: | | | | |
| Research and development | 11,318 | 12,086 | 12,194 | 12,649 |
| General and administrative | 2,379 | 2,658 | 2,347 | 2,782 |
| Total operating expenses | 13,697 | 14,744 | 14,541 | 15,431 |
| Loss from operations | (12,253) | (13,185) | (14,024) | (14,416) |
| Net interest income | 1,188 | 1,210 | 1,298 | 915 |
| Loss before income taxes | (11,065) | (11,975) | (12,726) | (13,501) |
| Provision for income taxes | (100) | | | |
| Net loss | $ (11,165) | $ (11,975) | $ (12,726) | $ (13,501) |
| Net loss per share basic and diluted | $ (0.79) | $ (0.80) | $ (0.81) | $ (0.86) |

| | Three Months Ended | | | |
|---|---|---|---|---|
| | March 31, 2000 | June 30, 2000 | September 30, 2000 | December 31, 2000 |
| | (In thousands, except per share data) | | | |
| Revenue: | | | | |
| Development funding, related parties | $ 575 | $ 442 | $ 419 | $ 195 |
| Development funding, other | | | | |
| Government grants and cooperative agreements | 52 | 99 | 69 | |
| Total revenue | 627 | 541 | 488 | 195 |
| Operating expenses: | | | | |
| Research and development | 7,071 | 8,000 | 9,129 | 10,623 |
| General and administrative | 1,739 | 1,819 | 1,599 | 2,003 |
| Total operating expenses | 8,810 | 9,819 | 10,728 | 12,626 |

| | Three Months Ended | | | |
|---|---|---|---|---|
| Loss from operations | (8,183) | (9,278) | (10,240) | (12,431) |
| Net interest income | 665 | 800 | 1,083 | 1,551 |
| Loss before income taxes | (7,518) | (8,478) | (9,157) | (10,880) |
| Provision for income taxes | | | | |
| Net loss | $ (7,518) | $ (8,478) | $ (9,157) | $ (10,880) |
| Net loss per share basic and diluted | $ (0.61) | $ (0.66) | $ (0.69) | $ (0.77) |



**SIGNATURES**

Pursuant to the requirement of Section 13 or 15(d) 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, in the City of Concord, State of California, on the 26th day of March, 2002.

CERUS CORPORATION

By: /s/ STEPHEN T. ISAACS

Stephen T. Isaacs
*President and Chief Executive Officer*

**POWER OF ATTORNEY**

Each person whose signature appears below constitutes and appoints Stephen T. Isaacs and Gregory W. Schafer, his true and lawful attorney-in-fact and agent, each acting alone, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any or all amendments to the Annual Report on Form 10-K and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ STEPHEN T. ISAACS<br>Stephen T. Isaacs | President, Chief Executive Officer and Director<br>*(Principal Executive Officer)* | March 26, 2002 |
| /s/ GREGORY W. SCHAFER<br>Gregory W. Schafer | Chief Financial Officer and Vice President, Finance<br>*(Principal Financial and Accounting Officer)* | March 26, 2002 |
| /s/ B.J. CASSIN | Chairman of the Board | March 26, 2002 |

| Signature | Title | Date |
|---|---|---|
| B.J. Cassin<br>/s/ BRUCE C. COZADD<br>Bruce C. Cozadd | Director | March 26, 2002 |
| /s/ JOHN E. HEARST<br>John E. Hearst | Director | March 26, 2002 |
| /s/ C. RAYMOND LARKIN, JR.<br>C. Raymond Larkin, Jr. | Director | March 26, 2002 |
| Wiliam R. Rohn | Director | March , 2002 |



**INDEX TO EXHIBITS**

| Exhibit Number | Description of Exhibit |
|---|---|
| 23.1 | Consent of Ernst & Young LLP, Independent Auditors. |
| 10.39 | Lease, dated December 17, 1999 between Cerus and Redwoods Office Center, L.P. |
| 10.40 | Lease, dated October 12, 2001 between Cerus and California Development, Inc. |