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FORM 10-K
(Annual Report)

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2003

OR

☐ **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 Number)
2411 Stanwell Dr. 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 ☒ No ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☒ No ☐

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. ☐

The approximate aggregate market value of the common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price of the registrant's common stock listed on the Nasdaq National Market, was $156,794,700.(1)

As of February 29, 2004, there were 22,104,766 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement in connection with the registrant's 2004 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than April 30, 2004, are incorporated by reference into Part III of this annual report on Form 10-K.

(1) Based on a closing sale price of $7.52 per share on June 30, 2003. Excludes 1,151,684 shares of the registrant's common stock held by executive officers, directors and affiliates at June 30, 2003.

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PART I

This report contains forward-looking statements. These forward-looking statements are based on our current expectations about our business and industry, and include, but are not limited to, statements concerning our plans or expectations concerning development and commercialization of our current products and product candidates; conduct of clinical trials of our product candidates; regulatory approvals; our ability to address certain markets; manufacturing and supply for our clinical trial and commercial requirements; reliance on a third party for a marketing, sales and distribution capability; evaluation of additional product candidates for subsequent clinical and commercial development; and potential outcomes of litigation. In some cases, these statements may be identified by terminology such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "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 our or our 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. We undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of this report.

Cerus and Helinx are U.S. registered trademarks of Cerus Corporation. INTERCEPT, INTERCEPT Blood, INTERSOL and Amicus are trademarks of Baxter International Inc.

Item 1. *Business*

Overview

We are developing medical systems, therapeutics and vaccines. Our most advanced programs are focused on systems to enhance the safety of blood products used for transfusion. The INTERCEPT Blood System, which is being developed in collaboration with subsidiaries of Baxter International Inc., is based on our proprietary Helinx® technology for controlling biological replication. The INTERCEPT Blood System is designed to inactivate viruses, bacteria, other pathogens and white blood cells. We also are pursuing therapeutic and vaccine technologies, including our Helinx technology, to treat and prevent serious diseases.

The INTERCEPT Blood System is designed to target and inactivate blood-borne pathogens, such as HIV and hepatitis B and C, as well as harmful white blood cells, while leaving intact the therapeutic properties of the blood components. The INTERCEPT Blood System inactivates a broad array of pathogens and has the potential to reduce the risk of transmission of pathogens for which testing is not completely effective or is not currently performed. We believe that the INTERCEPT Blood System also has the potential to inactivate new pathogens before they are identified and before tests are developed to detect their presence in donated blood.

We are conducting product development and commercialization activities with Baxter pursuant to agreements for the development, manufacturing and marketing of the INTERCEPT Blood System. These agreements provide for Baxter and us to generally share development expenses, except for the INTERCEPT Blood System for plasma, for which we are solely responsible for development expenses. These agreements also provide for Baxter's exclusive right and responsibility to market the systems worldwide and for us to receive a share of the gross profits from the sale of the systems.

The INTERCEPT Blood System for platelets has received CE Mark approval and is being marketed by Baxter in several countries in Europe. Baxter will need to complete validation studies and obtain reimbursement approvals in some individual European countries to market the product in those

countries. The level of additional product testing varies by country. In certain countries, including the United Kingdom, France and Germany, the system must be approved for purchase or use by a specific governmental or non-governmental (such as the Paul Ehrlich Institute in Germany) entity or entities in order for it to be adopted by a specific customer. Baxter has informed us that it has been notified by the regulatory body in France that the review of the INTERCEPT platelet marketing application is complete and the agency has granted authorization for the preparation, distribution and therapeutic use of the product. Commercial availability of the product in France is subject to successful completion of certain laboratory studies, publication of a decree in the Official Journal to register INTERCEPT platelets and define their specifications and reimbursement approval.

We completed our Phase III clinical trial of the INTERCEPT Blood System for platelets in the United States in March 2001 and have submitted data from this trial, along with several other modules of our pre-market approval application, to the United States Food and Drug Administration, or FDA. Based on discussions with the FDA, we are performing additional analyses of the clinical trial data and, if the outcome of such additional analyses is acceptable to the FDA, plan to conduct a supplemental clinical trial. Data from the additional analyses and supplemental clinical trial will need to be submitted to the FDA before we can complete our regulatory submission.

We are in various stages of the regulatory application process for the INTERCEPT Blood System for platelets in certain other countries in

which we are not expecting to receive significant revenue from product sales.

We are in late stage development of the INTERCEPT Blood System for plasma and have recently completed enrollment in the last of three planned Phase III clinical trials.

In September 2003, we terminated Phase III clinical trials of our INTERCEPT Blood System for red blood cells due to the detection of antibodies in two patients. As a result, we restructured our operations to focus on our pathogen inactivation products for platelets and plasma and our pipeline of therapeutics and vaccines. The restructuring was intended to reduce operating expenses and included a reduction in our workforce of approximately 25%. The observations from this trial do not affect the development or commercialization of the pathogen inactivation programs for platelets and plasma, which use a different technology and mechanism of action. We have begun an evaluation of the antibody detected in the red blood cell trial and are investigating whether process changes could prevent antibody formation and allow the modified red blood cell system to undergo clinical trials. These activities may take a long time to complete and may not be successful.

We are also developing a proprietary, versatile technology to stimulate the immune system to target and attack cancer cells and infectious diseases. This platform technology is based on specially designed strains of the bacterium *Listeria monocytogenes* . Our scientists have demonstrated that proprietary strains of *Listeria* are capable of inducing potent immune responses in laboratory tests. We believe that the combination of proprietary strains of *Listeria* with specific cancer antigens, such as Mesothelin, has the potential to harness the power of the immune system to selectively attack malignant cells. Additionally, we are further evaluating our *Listeria* platform technology with our Helinx technology for the development of potentially safe and potent therapies and vaccines for certain indications.

Two investigator-sponsored clinical trials are evaluating our Helinx technology in specific applications: our allogeneic cellular immune therapy (ACIT) technology, designed to improve the outcome of bone marrow transplantation procedures through use of T-cells treated with the Helinx technology and an Epstein-Barr virus (EBV) cellular vaccine are in Phase I clinical trials.

Cerus was incorporated in California in 1991 and reincorporated in Delaware in 1996. Information regarding Cerus' revenue, losses and total assets for the last three fiscal years can be found in the financial statements and related notes included elsewhere in this report.

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 80 million whole blood donations occur each year. Approximately 40 million of those donations occur in North America, Western Europe and Japan, the primary geographical markets for the INTERCEPT Blood System.

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, or blood clotting, 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, very rarely, 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), West Nile virus 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, babesiosis 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. More recently, West Nile virus has been transmitted through blood transfusions. 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 through interviews. In addition to required donor screening, diagnostic tests have been developed over time to detect the presence of certain infectious pathogens that are 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 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 HCV is mandatory in most blood centers in Europe, and is used by most blood centers in the United States. Although nucleic acid testing is more effective at detecting HIV and HCV in earlier stages of infection in a donor, it does not close the infectivity window completely. For example, transfusion recipients in the United States, Europe and Japan have been infected from blood transfusions for which nucleic acid testing failed to detect the virus. Furthermore, nucleic acid testing, like other testing currently performed on donated blood, is of 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, are not always 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, many infected blood products continue to 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 general volunteer donor blood.

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, quarantining 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 specifically detect the presence of all forms of harmful bacteria would be extremely expensive. As a result, the only test specific to a bacterium that is conducted in all blood products 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. We believe 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.

The INTERCEPT Blood System and Helinx Technology

We are developing the INTERCEPT Blood System with Baxter to address the problem of transmission of infectious diseases through blood transfusions. The INTERCEPT Blood System employs our proprietary nucleic-acid targeting Helinx technology. We have conducted studies that have demonstrated the ability of the Helinx technology to inactivate a broad array of viral and bacterial pathogens that may be transmitted in blood transfusions. We believe that the mechanism of action of our 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 the INTERCEPT Blood System is designed to inactivate rather than merely test for pathogens, the system also has 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 our 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.

The INTERCEPT Blood System is being designed to integrate into current blood collection, processing and storage procedures. Furthermore, we believe that the use of the INTERCEPT Blood System, 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.

Our Strategy

Our objective is to develop medical systems, therapeutics and vaccines that provide safer and more effective treatment options to patients. The INTERCEPT Blood System, based on our Helinx technology, is designed to inactivate viruses, bacteria, other pathogens and harmful white blood cells in blood components for transfusion. We also are pursuing therapeutic and vaccine technologies, including our Helinx technology, to treat and prevent serious diseases. Our strategy incorporates the following key elements:

Establish the INTERCEPT Blood System as the Standard of Care. Domestically, the target customers for the INTERCEPT Blood

System 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, we have developed strong relationships with prominent transfusion medicine experts in a number of these centers as well as in the broader medical communities worldwide. We intend to work with these experts to encourage support for the adoption of the INTERCEPT Blood System as the standard of care.

Use Strategic Alliances. We have received significant development funding from Baxter, and intend to leverage Baxter's manufacturing, marketing and distribution expertise and resources. We believe 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 us with access to an established marketing, sales and distribution network. The INTERCEPT Blood System is being designed to integrate into Baxter's current product line and into current blood collection, processing and storage processes. We are also collaborating with the U.S. Armed Forces on several initiatives intended to improve the safety and availability of the military's blood supply. We intend to continue to develop our products, including our pre-clinical vaccines program, together with partners that can provide direct funding and manufacturing, marketing and distribution resources and expertise.

Protect and Enhance Proprietary Position. We believe that the protection of our proprietary technologies is important to our business prospects and that our intellectual property position may create competitive barriers to entry into the blood component treatment market. We currently hold issued and allowed patents covering a number of fundamental aspects of our Helinx technology and our

blood component treatment system technology. We intend to continue to pursue our patent filing strategy and to vigorously defend our intellectual property position against infringement.

Product Development

We are developing systems to inactivate infectious pathogens and harmful white blood cells in platelets, FFP and red blood cells and vaccine platforms for cancer and infectious diseases. We have incurred total research and development expenses of $52.5 million, $56.4 million and $48.2 million for the years ended December 31, 2003, 2002 and 2001, respectively. The following table identifies our product development programs:

Program	Therapeutic Indication	Cerus Product in Development	Development Status	Collaborator
Platelets	Surgery, cancer chemotherapy, transplantation, bleeding disorders	INTERCEPT Blood System for platelets	CE Mark received and product is being marketed in certain countries in Europe; United States Phase III clinical trial completed, additional data analyses and supplemental clinical trial required	Baxter
Plasma (FFP)	Surgery, transplantation, bleeding disorders	INTERCEPT Blood System for plasma	Phase IIIa and IIIb clinical trials completed; Phase IIIc clinical trial patient enrollment completed	Baxter
Red Blood Cells	Surgery, transplantation, anemia, cancer chemotherapy, trauma	INTERCEPT Blood System for red blood cells	Phase III clinical trials were terminated in September 2003 due to the detection of antibodies in two patients; research on potential modifications to the system is ongoing	Baxter
Vaccine Platform	Cancer, infectious diseases	Broad platform using attenuated *Listeria* strains to stimulate immune response	Pre-clinical research and development	

Clinical Trial Design. We conduct 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 patient exposure to pooled, manually collected platelets from different donors.

We estimate the production of platelets in 2003 to have been 2.2 million transfusion units in North America, 1.4 million transfusion units in Western Europe and 0.7 million transfusion units in Japan. Based on the Report on Blood Collection and Transfusion in the United States in 2001 prepared by the National Blood Data Resource Center, the estimated base cost for a transfusion unit of apheresis platelets ranged from approximately $461 to $489, and the estimated base cost for a transfusion unit of random donor platelets ranged from approximately $209 to $345. These estimates include donor screening and diagnostic tests, such as those for HIV, HTLV, HBV and HCV. Blood centers may also charge for additional procedures, such as gamma irradiation and CMV screening. The frequency of use and additional charge for each procedure vary widely.

INTERCEPT Blood System for Platelets. The INTERCEPT Blood System for platelets uses our Helinx compound, amotosalen, 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. Viruses, bacteria or other pathogenic cells cannot cause an infection if they cannot replicate. A similar reaction with the nucleic acid in white blood cells inhibits the activity that is responsible for certain adverse transfusion-related reactions. Studies with pre-clinical models have indicated that, following illumination and transfusion, the amotosalen and its breakdown products are rapidly metabolized and excreted. As a further safety measure, the INTERCEPT Blood System for platelets employs a removal process designed to reduce the amount of residual amotosalen and breakdown products following illumination.

Cerus and Baxter have designed the INTERCEPT Blood System for platelets to be used in the blood center. The system consists of a disposable processing set, containing the amotosalen compound and a compound adsorption device (CAD), and an illumination device to deliver light to trigger the inactivation reaction. The collection of the platelets is performed, as normal except that two-thirds of the donor's plasma that would normally be collected with the platelets is replaced by a platelet additive solution, called INTERSOL. The platelets are then transferred through a pouch containing the amotosalen compound into an illumination container. The mixture of platelets, amotosalen and INTERSOL is illuminated for approximately three to six minutes. Following the CAD treatment, a passive process that takes approximately four to sixteen hours, the platelets are transferred to the final storage container, to be stored until ready to be transfused.

Development Status. In Europe, the INTERCEPT Blood System for platelets has received CE Mark approval for use with pooled whole blood platelets collected using the buffy coat process and for apheresis platelets collected on Baxter's Amicus apheresis platform. A CE Mark also has been received for preparation sets for platelets collected using the Haemonetics and Cobe apheresis systems. We completed our Phase III clinical trial of the INTERCEPT Blood System for platelets in the United

States in March 2001 and have submitted data from this trial, along with several other modules of our pre-market approval application, to the FDA. Based on discussions with the FDA, we are performing additional analyses of the clinical trial data and, if the outcome of such additional analyses is acceptable to the FDA, plan to conduct a supplemental clinical trial. Data from the additional analyses and supplemental clinical trial will need to be submitted to the FDA before we can complete our regulatory submission.

Pathogen Inactivation Studies. Published results of laboratory and animal model studies have demonstrated the efficacy of the INTERCEPT Blood System for the inactivation of a broad array of viral, bacterial and parasitic pathogens transmitted through platelet

transfusions, including HIV, CMV, HTLV, model hepatitis viruses, West Nile Virus and the virus that causes Severe Acute Respiratory Syndrome (SARS), 19 strains of bacteria, including syphilis, and the parasites that cause malaria, leishmaniasis and Chagas' disease. A pre-clinical study conducted 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 Blood System, did not transmit the viruses to susceptible animals. We have tested these pathogens at and above concentrations that we believe 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 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. We have successfully completed and published the results of a comprehensive series of pre-clinical safety studies for the INTERCEPT Blood System for platelets. Completed safety studies of amotosalen and the INTERCEPT Blood System for platelets 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 strong safety profile for the INTERCEPT Platelet System.

Clinical Trials. In March 1996, we completed a Phase Ia single-blind, randomized clinical trial in 24 healthy human subjects at 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 Ib.

In September 1996, we completed a Phase Ib single-blind, randomized, cross-over clinical trial in ten 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 our pre-clinical data, reflected acceptable safety margins and cleared the INTERCEPT Platelet System for a Phase IIa clinical trial.

In November 1996, we 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. The average post-transfusion recovery of five-day-old platelets treated with our 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, 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, we 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 Blood 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 Phase 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. We believe, based on discussions with the FDA, that the post-transfusion recovery and lifespan of platelets following treatment with the INTERCEPT Blood System are clinically acceptable.

In November 1998, we 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 our experience in patients prior to a Phase III trial, we 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 us 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, we completed our European Phase III euroSPRITE clinical trial which compared conventional platelets with treated pooled random donor platelets in 103 thrombocytopenic patients (patients with low platelet counts and at high risk for bleeding) requiring

repeated platelet transfusions for up to 56 days. The study was conducted in four European countries and served as the pivotal trial for the CE Mark approval in Europe, which was received in 2002. The whole blood 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 Blood System.

The trial had co-primary endpoints: corrected count increment and platelet count increment, each measured 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 Blood 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 Blood System for platelets.

We also completed a 21-patient clinical trial in Europe to qualify the system for its commercial configuration and completed a 43-patient clinical trial in Europe to extend qualification of the system to platelets collected by the Amicus apheresis platform.

In March 2001, we completed our 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 patients who received control platelets 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 number 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 significant difference between the group of patients who received INTERCEPT platelets and the group of patients who received untreated platelets, but these differences did not affect the primary trial endpoint of demonstrating equivalence in the proportion of patients with moderate bleeding between the two groups. Although differences were observed for specific adverse event terms, adverse events and serious adverse events in the aggregate were not statistically different between the groups and were consistent with expectations in the seriously ill patient population undergoing intensive chemotherapy. Pursuant to discussions with the FDA, we are conducting additional analyses. The additional analyses include blinded reviews of certain adverse event data by independent experts.

The Phase III United States SPRINT trial was designed to assess the therapeutic efficacy of platelets treated with the INTERCEPT Blood System for platelets collected by Baxter's apheresis collection system. In order to obtain FDA approval of the INTERCEPT Blood System for use in treating pooled random donor platelets, we will need to complete development of an additional configuration of our 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 Blood 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 Blood 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.

Plasma Program

Plasma 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 for transfusion or made available for fractionation into plasma derivatives. Plasma 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 and patients with chronic liver disease or certain genetic clotting factor deficiencies, and to treat certain diseases that require plasma exchange therapy.

We estimate the production of FFP in 2003 to have been 3.7 million units for transfusion in North America, 2.2 million transfusion units in Western Europe and 2.3 million transfusion units in Japan. Based on the Report on Blood Collection and Transfusion in the United States in 2001 prepared by the National Blood Data Resource Center, the estimated base price of a 250 ml transfusion unit of FFP in the United States ranged from approximately $51 to $55. A typical therapeutic transfusion consists of four transfusion units of FFP.

INTERCEPT Blood System for Plasma. The INTERCEPT Blood System for plasma uses the same psoralen compound and illumination device and a CAD similar to that being used with the INTERCEPT Blood System for platelets. In the INTERCEPT Blood System for plasma, untreated plasma is transferred to a disposable container with amotosalen. The mixture of amotosalen and plasma is then illuminated for approximately three to five 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 Blood System for plasma has completed patient enrollment in the last of three planned Phase III clinical trials in the United States.

Pathogen Inactivation Studies. Published results of laboratory studies to date have demonstrated the efficacy of the INTERCEPT Blood System for plasma for the inactivation of a broad array of pathogens transmitted through blood transfusion, including HIV, model hepatitis viruses and syphilis. A pre-clinical study conducted in collaboration with the NIH demonstrated that FFP contaminated with high levels of hepatitis B virus or hepatitis C virus, and treated with the INTERCEPT Blood System, did not transmit the viruses to susceptible animals. We have conducted laboratory studies indicating the efficacy of the INTERCEPT Blood System for the inactivation of the parasite that causes Chagas' disease in FFP. Because of the mechanism of action of the INTERCEPT Blood System for plasma, we believe that the system also inhibits white blood cell activity. To date, we have conducted no studies to detect inhibition of white blood cell activity in FFP.

Coagulation Function Studies. We have 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. We have performed laboratory studies measuring the coagulation function activity of various clotting factors in FFP after photochemical treatment, CAD treatment, freezing and thawing. We believe 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. We have successfully completed and published results of a series of pre-clinical safety studies for the INTERCEPT Blood System for plasma. 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 strong safety profile for the INTERCEPT Blood System for plasma. While we believe that all pre-clinical safety studies required for regulatory approval have been completed, regulatory authorities may require additional pre-clinical safety studies to be performed.

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

In November 1998, we 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 Blood System were comparable to those of subjects receiving untreated FFP. There were no safety issues attributable to transfusion of the treated FFP.

In 1999, we completed a Phase IIb clinical trial of the INTERCEPT Blood System for plasma. 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, we completed a Phase IIIa clinical trial of the INTERCEPT Blood System for plasma. 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 Blood 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, we completed a Phase IIIb clinical trial of the INTERCEPT Blood System for plasma. 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 has recently been completed 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.

INTERCEPT Blood System for Red Blood Cells. The INTERCEPT Blood System for red blood cells 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 us, 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. Phase III clinical trials of the INTERCEPT Blood System for red blood cells were terminated in September 2003 due to the detection of antibodies in two patients. The observations from this trial do not affect the development or commercialization of the pathogen inactivation programs for platelets and plasma, which use a different technology and mechanism of action. We have begun an evaluation of the antibody and are investigating process changes that could prevent antibody formation and allow the modified red blood cell system to undergo clinical trials. These activities may take a long time to complete and may not be successful.

Pathogen Inactivation Studies. Published results of laboratory studies have demonstrated the efficacy of the INTERCEPT Blood System for the inactivation of a broad array of viral, bacterial and parasitic pathogens, including West Nile Virus and the virus that causes SARS, with preservation of red blood cell function. We have also conducted laboratory studies that have indicated inhibition of white blood cell activity.

Pre-Clinical Safety Studies. We have successfully completed and published results of a number of pre-clinical safety studies for the INTERCEPT Blood System for red blood cells. Completed safety studies include acute and chronic toxicology, reproductive toxicology, general pharmacology, ADME, genotoxicity and carcinogenicity studies.

Clinical Trials. In May 1999, we completed a Phase Ia clinical trial of the INTERCEPT Blood System for red blood cells. 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, we completed a Phase Ib clinical trial of the INTERCEPT Blood System for red blood cells. 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, we completed a Phase Ic clinical trial of the INTERCEPT Blood System for red blood cells. 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 blood cells exceeded the commonly accepted blood bank standard of 75%. In the second part of the study, 11 additional subjects received full unit transfusions of 35 day-old INTERCEPT red blood cells. The full unit transfusions were well tolerated.

In January 2002 and March 2002, we initiated Phase III clinical trials of the INTERCEPT Blood System for red blood cells for acute transfusion support and for chronic transfusion support, respectively. The chronic trial enrolled patients requiring red blood cell transfusion support for the treatment of chronic anemia due to hereditary disorders, such as sickle cell disease or thalassemia. Both Phase III trials were terminated in September 2003 after two patients in the chronic trial developed antibodies to red blood cells treated with S-303. The two patients showed an antibody response but no clinical adverse events after transfusion with the S-303 treated red blood cells. The antibody response was discovered using a standard blood test that was employed as part of the clinical protocol.

We plan to evaluate the available clinical data from the terminated Phase III clinical trials to determine the appropriate course of action for our investigational pathogen inactivation system for red blood cells. If we are successful in identifying process changes that could prevent antibody formation, it is not known what stages of clinical testing would be necessary to be completed for the reconfigured system.

Vaccine Platform Program

Listeria Platform. We are developing a proprietary, versatile technology to stimulate the immune system to target and attack cancer cells and infectious diseases. This platform technology is based on specially designed strains of the bacterium *Listeria monocytogenes* . Our scientists have demonstrated that proprietary strains of *Listeria* are capable of inducing potent immune responses in laboratory tests. We believe that the combination of proprietary strains of *Listeria* with specific cancer antigens, such as Mesothelin, has the potential to harness the power of the immune system to selectively attack malignant cells. Additionally, we are futher evaluating our *Listeria* platform technology with our Helinx technology for the development of potentially safe and potent therapies and vaccines for certain indications.

Mesothelin. We acquired certain exclusive rights to a novel cancer antigen, Mesothelin, from The Johns Hopkins University. We are using Mesothelin in combination with our proprietary cancer vaccine platform to develop therapeutic vaccines for the treatment of pancreatic and ovarian cancers. Mesothelin is an antigen that is frequently expressed in primary pancreatic and ovarian malignancies, but has limited expression in normal tissue. Research conducted at JHU has demonstrated that pancreatic cancer patients who responded to a Mesothelin-based prototype vaccine (not using our platform technology) generated an immune response against the antigen. We are developing a therapeutic vaccine that is designed to incorporate the Mesothelin antigen in our proprietary *Listeria* vaccine platform to potentially stimulate the patient's immune system to selectively recognize and kill pancreatic and ovarian tumor cells that express the Mesothelin cancer antigen.

Development Status. Our *Listeria* -based vaccine program is in pre-clinical research and development.

Investigator-Sponsored Clinical Trials of Helinx Technology

We are collaborating with the National Marrow Donor Program, which is conducting a Phase Ib clinical study of our ACIT program in bone marrow transplants from unrelated donors.

A Phase I clinical trial of an experimental EBV cellular vaccine utilizing our Helinx technology is being conducted at Johns Hopkins University, and is supported in part by a grant from the National Institutes of Health.

We do not plan to provide funding for these investigator-sponsored clinical trials or for further development of these programs and plan to conduct research and development supporting these applications of our Helinx technology to the extent that such activities are funded by outside sources.

Future Product Development

In addition to our plans to pursue the therapeutic potential of our Helinx and vaccine platform technologies, we may also explore other development areas where we can address large, unmet medical needs.

Alliance with Baxter

We have established an alliance with Baxter for the development of the INTERCEPT Blood System. Under two primary development, manufacturing and marketing agreements, Baxter and we generally share development activities with the primary development activity for the compounds and the pre-clinical and clinical studies performed by us and the primary development activity for the system disposables and devices performed by Baxter. Upon commercialization, we provide the inactivation compounds and Baxter is responsible for manufacturing and assembling the system disposables and illumination devices. Baxter is also responsible for marketing, selling and distributing the system. 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 Blood System for Platelets. We have a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Blood System to inactivate infectious pathogens in platelets used for transfusion. This agreement provides for Baxter and us generally to share system development costs equally, subject to mutually determined budgets established from time to time, and for us 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 is responsible for manufacturing and marketing the INTERCEPT Blood System for platelets. Revenue sharing payments due to us from sales of the INTERCEPT Blood System for platelets in Europe are currently being remitted by Baxter on our behalf to Baxter Capital Corporation, a financial subsidiary of Baxter International Inc., due to a dispute over the timing of repayment of a loan from Baxter Capital to us. We do not expect to receive revenue sharing payments from Baxter until this dispute is resolved.

Agreement with Baxter for the Development of the INTERCEPT Blood System for Red Blood Cells and INTERCEPT Blood System for Plasma. We also have a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Blood System to inactivate viruses, bacteria and other infectious pathogens in red blood cells and fresh frozen plasma for transfusion. This agreement provides for Baxter and us generally to share red blood cell system development costs equally, subject to mutually determined budgets established from time to time. We are solely responsible for funding the development costs of the INTERCEPT Blood System for plasma. Baxter has an exclusive, worldwide distribution license and will be responsible for manufacturing and marketing the INTERCEPT Blood System for red blood cells and INTERCEPT Blood System for plasma following regulatory approvals. The agreement also provides for an equal sharing of revenue from sales of red blood cell system disposables, and for us to receive 75% and Baxter to receive 25% of revenue from sales of plasma system disposables, in each case after each party is reimbursed for its

cost of goods and a specified percentage, not to exceed 14% of revenue, is retained by Baxter for marketing and administrative expenses. The termination of Phase III clinical trials of the red blood cell system does not affect the terms of the agreement, but will significantly delay the development of, and any potential revenue from, sales of the red blood cell system.

Funding from Baxter. As of December 31, 2003, we have 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, have received proceeds from a $50.0 million loan from Baxter Capital and have recognized approximately $30.4 million in milestone and development funding revenue from Baxter, since inception. Baxter has advised us that Baxter International Inc. and Subsidiaries Pension Trust is not an affiliate of Baxter. Baxter Capital has commenced legal proceedings against us seeking immediate repayment of amounts outstanding under the loan. Baxter Capital alleges that changes in our business constitute a default under the terms of the loan. Development funding is in the form of balancing payments made by Baxter to us, if necessary, to reimburse us for development spending in excess of the levels determined by Baxter and us.

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

Agreement with Kirin Brewery Co. Ltd.

In January 2001, we entered into a collaborative agreement with the Pharmaceutical Division of Kirin to develop and market products for stem cell transplantation based on our Helinx technology. Under the terms of the agreement, we will jointly develop the products with Kirin. We received an initial license fee of $1 million. The license fee is being deferred and recognized as development funding ratably over the development period. We may not receive additional funding from Kirin. Although the agreement calls for Kirin to fund all development expenses for the Asia-Pacific region and a portion of our development activities aimed at obtaining product approval in the United States, no such development activities co-funded by Kirin are currently ongoing. Upon product approval, Kirin has exclusive rights to market the products in the Asia-Pacific region, including Japan, China, Korea and Australia, and we will receive a specified share of product revenue, including a royalty and reimbursement of our cost of goods. We retain 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, we were awarded a $3.5 million cooperative agreement by the Army Medical Research Acquisition Activity division of the Department of Defense. In September 2002 and May 2003, we were awarded additional $6.5 million and $6.2 million cooperative agreements, respectively, both of which were awarded to continue funding of projects to develop our 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 agreements, we are conducting research on the inactivation of infectious pathogens, including unusual viruses, bacteria and parasites, which are of particular concern to the Armed Forces. We are collaborating with investigators at Walter Reed Army Institute of Research to 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.

Product Engineering

The INTERCEPT Blood System comprises mechanical instruments that activate the pathogen inactivation process and disposables that include plastic containers and tubing, inactivation compounds and other fluids, and compound adsorption devices. The design and engineering of the system requires substantial effort. Although we collaborate in these efforts, the bulk of this work is undertaken by Baxter.

Manufacturing and Supply

We have used, and intend to continue to use, third parties to manufacture and supply the inactivation compounds for our systems for use in clinical trials and for the commercialization of our products in development. We have no experience in manufacturing products for commercial purposes and do not have any manufacturing facilities. Consequently, we are dependent on contract manufacturers for the production of compounds and on Baxter for other system components for development and commercial purposes.

Under our agreements with Baxter, we are responsible for developing and delivering our 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.

To provide the inactivation compounds for the INTERCEPT Blood System for platelets and INTERCEPT Blood System for plasma, we have contracted with one manufacturing facility for synthesis of amotosalen. Under this contract, we are not subject to minimum annual purchase requirements. If specified quantities of amotosalen are not purchased in any year, however, we are required to pay a maintenance fee of up to $50,000 for such year. We currently have a stock of compound sufficient to support the anticipated remaining product development planned for the INTERCEPT Blood System for platelets and INTERCEPT Blood System for plasma, and to support near-term sales of the INTERCEPT Blood System for platelets in Europe.

Our contract manufacturers and we purchase certain raw materials from a limited number of suppliers. While we believe 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 to obtain from alternative suppliers any of the materials used to manufacture our compounds, if required, would limit our ability to manufacture our compounds.

Marketing, Sales and Distribution

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 many countries of Western Europe and in 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. In Europe, the largest markets for our products are in Germany, the United Kingdom and France. Decisions on product adoption are centralized in the United Kingdom. In Germany, decisions on product adoption are expected to be on a blood center-by-blood center basis. We have not received in-country approvals to market our platelet system in Germany or the United Kingdom, and certain additional activities are required before we can market the system in France.

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. Our products may require significant changes to our potential customers' space and staffing requirements and require significant capital investment. 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. Some blood product is consumed as a result of our pathogen inactivation process. If the reduction of blood product leads to increased costs,

or requires changes in clinical regimens, customers may not adopt our product. In addition, our products do not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens may inhibit their acceptance. Our products may be inappropriate for certain patients, which could reduce the potential market size. In addition, healthcare professionals may require further safety information or additional studies before adopting our products. Baxter's ability to successfully commercialize our 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.

Baxter is responsible for the worldwide marketing, sales and distribution of the INTERCEPT Blood System. 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 System.

Competition

We believe that the INTERCEPT Blood System has certain competitive advantages over competing pathogen inactivation methods that are either on the market, or in development. The INTERCEPT Blood System is 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 that takes the blood product away from the blood center. The INTERCEPT Blood System is 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. There are currently no competitors that have pathogen inactivation methods approved or in clinical trials for platelets. In addition to competition from other pathogen inactivation methods, we expect to encounter competition from other approaches to blood safety, including methods of testing blood products for pathogens.

We 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. We believe that the INTERCEPT Blood System 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, 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 involves a high degree of risk, and there can be no assurance that our product development efforts will result in any commercially successful products.

Patents, Licenses and Proprietary Rights

Our success depends in part on our 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 us. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. As of December 31, 2003, we owned 67 issued or allowed United States patents and 60 issued or allowed

foreign patents. Our patents expire at various dates between 2009 and 2018. In addition, we have 27 pending United States patent applications and have filed 20 corresponding patent applications under the Patent Cooperation Treaty, which are currently pending in Europe, Japan, Australia and Canada, and of which eight are also pending in China and six of which are also pending in 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 12 United States patents relating to vaccines, as well as related foreign patents. Proprietary rights relating to our 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, us will afford protection against competitors or that any pending patent applications now or hereafter filed by, or licensed to, us will result in patents being issued. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

Government Regulation

Our products and we 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.

The FDA regulates the INTERCEPT Blood System as a biological medical device. The FDA's Center for Biologics Evaluation and Research is principally responsible for regulating the INTERCEPT Blood System. In addition to regulating our product, CBER also regulates the blood collection centers and the blood products they prepare using our medical device.

Before the FDA determines whether to approve our products, we expect our approval applications to be reviewed by the Blood Products Advisory Committee, or BPAC, an advisory committee convened by and reporting to the FDA. The BPAC will make a recommendation to the FDA for, or against, approval. Before a medical device may be marketed in the United States, the FDA must clear a premarket notification (a 510(k)) or approve a premarket approval 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. 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.

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 (for medical devices) or an investigational new drug application (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 FDA will require a PMA for each of the systems for platelets, plasma and red blood cells.

Our European investigational plan is based on the INTERCEPT Blood System being categorized as Class III drug/device combinations under the Medical Device Directives of the European Union. 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. The INTERCEPT Blood System for platelets received the CE Mark in October 2002. Separate CE Mark certifications must be received for Baxter to sell the INTERCEPT Blood System for plasma and INTERCEPT Blood System for red blood cells in the European Union. Many individual European countries require additional in-country studies to support an approval to market the products in such countries.

Baxter is using a modular process for its PMA application for the INTERCEPT Blood System for platelets. 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.

In addition to the regulatory requirements applicable to our products and us, 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 be required to obtain approved license supplements from the FDA before using the INTERCEPT Blood System. 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 Baxter's requests for regulatory approval to market the INTERCEPT Blood System, we conduct 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. We believe that, in deciding whether the INTERCEPT Blood System 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. We have conducted many toxicology studies designed to demonstrate the INTERCEPT Blood System's safety. There can be no assurance that regulatory authorities will not require further toxicology or other studies of our products. Based on discussions with the FDA and European regulatory authorities, we believe 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, our clinical trial programs for the INTERCEPT Blood System consists of studies that differ from typical Phase I, Phase II and Phase III clinical studies.

All of our clinical trials have been and are being conducted using prototype system disposables and devices. We plan to perform laboratory studies to demonstrate equivalency between the prototype and the commercial configuration. We cannot be certain that these studies will be successful or the FDA will not require additional studies, which could delay commercialization. If we decide to seek FDA approval of the INTERCEPT Blood System for platelets for use in treating pooled random donor platelets, additional clinical studies will be required. 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 Blood System. However, we intend initially to seek FDA approval of the INTERCEPT Blood System for platelets configured for

Baxter's apheresis collection equipment. If we determine that compatibility with other equipment is desirable, additional processing procedures and system configurations will need to be developed. We believe that the FDA will also require supplemental clinical data before approving its system for use with platelets collected using other equipment.

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.

Our ability to commercialize our 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 our products.

Employees

As of February 29, 2003, we had 120 employees, 81 of whom were engaged in research and development and 39 in general and administrative. None of our employees are covered by collective bargaining agreements, and we believe that our relationship with our employees is good.

Available Information

We maintain a website at www.cerus.com; however, information found on our website is not incorporated by reference into this report. We make available free of charge on or through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

RISK FACTORS

Our business faces significant risks. If any of the events or circumstances described in the following risks actually occur, our business may suffer, the trading price of our common stock could decline and our 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.

If our pre-clinical and clinical trials are not successful or the data are not considered sufficient by regulatory authorities to grant marketing approval, Baxter and we will be unable to commercialize our products and generate revenue.

Except for the INTERCEPT Blood System for platelets, which has received CE Mark approval and regulatory approval in certain countries in Europe, we have no products that have received regulatory approval for commercial sale and are being marketed. 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. 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 government regulations before the products can be approved for commercial sale.

In 2002, the INTERCEPT Blood System for platelets received CE Mark approval in Europe. Our development and marketing partner,

Baxter Healthcare Corporation, will need to complete validation studies and obtain reimbursement approvals in some individual European countries to market our products in those countries. In certain countries, including the United Kingdom, France and Germany, the system must be approved for purchase, reimbursement or use by a specific governmental or non-governmental (such as the Paul Ehrlich Institute in Germany) entity or entities in order for it to be adopted by a specific customer. The level of additional product testing varies by country, but could take a long time to complete.

We completed our Phase III clinical trial of the INTERCEPT Blood System for platelets in the United States in March 2001 and have submitted data from this trial, along with several other modules of our pre-market approval application, to the FDA. Based on discussions with the FDA, we are performing additional analyses of the clinical trial data. The additional analyses are blinded reviews of certain data by independent experts. If the results of these analyses are determined satisfactory by the FDA, we plan to conduct a supplemental clinical trial that will need to be completed and data from the trial submitted to the FDA before we can complete our regulatory submission. The FDA may not find the results of our analyses or data from any additional clinical trials to be acceptable for approval. Before we begin a supplemental clinical trial, we will need to gain concurrence with the FDA on our trial design. We may not be able to reach concurrence on the size, scope or design of the study.

We have completed Phase IIIa and Phase IIIb clinical trials of the INTERCEPT Blood System for plasma in the United States and have recently completed patient enrollment in a Phase IIIc clinical trial. We have not submitted any applications for regulatory approval of the INTERCEPT Blood System for plasma in the United States, Europe or any other regions.

As a result of the termination of Phase III clinical trials of our red blood cell system due to the detection of antibodies in two patients, we are conducting additional research activities on our red blood cell system to determine if the system can be reconfigured to prevent antibody formation and potentially undergo clinical testing. We may not be successful in this research. If we are successful, it is not known what stages of clinical testing would be necessary to be completed for the reconfigured system. If we are unsuccessful in developing a modified red blood cell system that can complete clinical

testing, then we may never realize a return on our development expenses incurred to date in this program.

Clinical trials in particular are expensive and have a high risk of failure. Any of our product candidates may fail in the testing phase or may not achieve results sufficient to 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 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. The blood centers that treat blood components with the INTERCEPT Blood System for use in clinical trials must comply with Good Manufacturing Practices and are subject to FDA audit. We are aware of exceptions to GMP in some of the blood centers that processed plasma units for our clinical trials that may be unacceptable to the FDA. 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, require other studies to be performed or cause a program to be terminated, even if other studies or trials relating to a program are successful.

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

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. Our products may require significant changes to our potential customers' space and staffing requirements and require significant capital investment. 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. Some blood product is consumed as a result of our pathogen inactivation process. If the reduction of blood product leads to increased costs, or requires changes in clinical regimens, customers may not adopt our product. In addition, our products do not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens may inhibit their acceptance. Our products may be inappropriate for certain patients, which could reduce the potential market size. In addition, some potential customers have indicated that further safety information or additional studies would be required before adopting our products. Baxter's ability to successfully commercialize our 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. If our products fail to achieve market acceptance, we may never become profitable.

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;
- product advertising and promotion; and
- product reimbursement

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. Before the FDA determines whether to approve our products, we expect our approval applications to be reviewed by the Blood Products Advisory Committee, or BPAC, an advisory committee convened by and reporting to the FDA. The BPAC will make a recommendation to the FDA for, or against, approval. If the BPAC were to recommend approval of one or more of our products, the FDA would not necessarily be required to approve those products. If the BPAC were to recommend against approval of one or more of our products, it is likely that the FDA would not approve those products.

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. For example, the FDA is considering implementing standards for the recovery and survival of stored platelets. Some platelets are consumed in our pathogen inactivation process. If we are unable to meet new or existing FDA standards for the recovery and survival of platelets, we will be unable to market our platelet system in the United States. 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 vary by country, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations. 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 a long time to complete. Failure to obtain necessary regulatory approvals or any other failure to comply with regulatory requirements could result in reduced revenue and earnings. In some countries, we may also need to obtain government approvals for reimbursement in order for our product to be adopted. Reimbursement levels in some countries are determined by annual budgeting processes, which, in addition to affecting product adoption, will affect the price we will be able to charge for our products.

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 are 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 to 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 or European regulatory authorities before using products processed with our pathogen inactivation systems. This requirement or regulators' 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.

Customer adoption of our products will be affected by the availability of reimbursement from governments or other third parties.

Sales of our products may be affected by the availability of reimbursement from governments or other third parties, such as insurance companies. It is difficult to predict the reimbursement status of newly approved, novel medical products. In certain foreign markets, governments have issued regulations relating to the pricing and profitability of medical products and medical products companies. There have been proposals in the United States, at both the federal and state government level, to implement such controls. The growth of managed care in the United States has also placed pressure on the pricing of medical products. These pressures can be expected to continue and may limit the prices Baxter and we can obtain for our products.

A small number of customers will determine market acceptance of our pathogen inactivation systems.

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. 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 many countries in Western Europe and in 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. In Europe, the largest markets for our products are in Germany, the United Kingdom and France. Decisions on product adoption are centralized in the United Kingdom. In Germany, decisions on product adoption are expected to be on a blood center-by-blood center basis. We have not received in-country approvals to market our platelet system in Germany or the United Kingdom, and certain additional activities are required before we can market the system in France. The National Blood Service has indicated that significant additional steps will need to be completed for their consideration of implementation of our platelet system in England. If we do not receive approvals to market our products in these countries, or if the products are not adopted in these countries, our potential product revenue in Europe will be significantly decreased.

We rely heavily on Baxter for development funding, product engineering, 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, 2003, we have received $46.7 million in equity investments from Baxter and $25.9 million from Baxter International Inc. and Subsidiaries Pension Trust, a $50.0 million loan from Baxter Capital Corporation and we have recognized $30.4 million in development funding 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 engineering, 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 design or 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 the INTERCEPT Blood System for regulatory approval or the market introduction and subsequent sales of the systems. Moreover, the inclusion of components manufactured by others could require us to seek new approvals from 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 System. If Baxter is unable to market the products successfully, we may need to develop our own capabilities to supplement Baxter's marketing efforts. If our agreements with Baxter are terminated, 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 increase our costs and, if our agreements with Baxter were terminated, would delay commercialization of our pathogen inactivation systems.

- *We share control over management decisions* . Baxter and we share responsibility for managing the development programs for the platelet and red blood cell pathogen inactivation systems.

Management decisions are made by a governance committee, which has equal representation from both Baxter and us. Day to day sales and marketing decisions are made by Baxter. 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.

- *Baxter can terminate our development and commercialization agreements, fail to perform or the platelet agreement may not be renewed* . Any development program under the agreements may be terminated by either party, with 90 days' notice in the case of the platelet program, or 270 days' written notice in the case of the plasma or red blood cell programs. The development and commercialization agreement for the platelet system expires in December 2008. The agreement provides for both parties to make good faith efforts to negotiate one or more three-year renewals unless either party provides written notice of termination no later than 12 months prior to the expiration date. Delays or setbacks, such as the clinical trial termination that recently occurred in our red blood cell program, in any of our shared development programs might increase the risk that Baxter would terminate or reduce its funding commitments to one or more programs. If Baxter terminates the agreements, the platelet agreement is not renewed or Baxter 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 dispute with Baxter Capital Corporation may affect our relationship with Baxter Healthcare Corporation* . Baxter Capital Corporation and Baxter Healthcare Corporation are both subsidiaries of Baxter International Inc. Although these companies are separate subsidiaries within Baxter International Inc., our dispute with Baxter Capital over the repayment terms of the $50.0 million loan could adversely affect our joint efforts to develop and commercialize the INTERCEPT Blood System.

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

Significant clinical trial delays would impair our ability to commercialize our products and could allow competitors to bring products to market before we do. 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 or delays in the supply of clinical product material, could also delay our clinical trials. Our product development costs will increase if we have additional delays in testing or approvals.

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 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. Competitors or potential competitors may 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 platelets and plasma. 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, including tests for bacteria in platelets. Several companies are developing tests for West Nile Virus in blood products, although none have been approved for sale to date. Development of any of these technologies could impair the potential market for our products.

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

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. These compounds and other components have never been produced in commercial quantities. We have an agreement with a manufacturer to produce commercial quantities of amotosalen, which is the compound used in our platelet and plasma systems. We currently do not have any other third-party manufacturing agreements in place for commercial production of other compounds or components. Any additional 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. In the United States, studies related to the platelet system disposable and compound manufacturing need to be completed and included in FDA submissions before the FDA would consider the applications for approval. Efforts to modify the design for manufacturing of our plasma system continue, and the timing of our regulatory submission for the plasma system is dependent on the successful completion of this design, which is uncertain.

Baxter has advised us that it intends to purchase certain key components of the pathogen inactivation systems from a limited number of suppliers. Contracts for the long-term supply of certain components have not yet been signed. 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.

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

If we fail to develop commercial versions of the systems on schedule, our potential revenue would be delayed or diminished and our competitors may be able to bring products to market before we do. The system disposables and instruments 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 acceptability of the commercial configuration and 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.

In addition, the design and engineering effort required to complete the final commercial product is substantial and time-consuming. As with any complex development effort, we expect to encounter design, engineering and manufacturing issues. Such issues have previously arisen, sometimes unexpectedly, and solutions to these issues have not always been readily forthcoming. Additional unforeseen design, engineering and manufacturing issues may arise in the future, which could increase the development cost and delay commercialization of our products.

We will need to establish a sufficient shelf life for the components of our products before the FDA will approve our products for sale.

Product stability studies to establish the shelf life of our system disposables have not yet demonstrated a sufficient shelf life. Certain platelet and plasma system disposables and packaging are being redesigned, and product stability will need to be validated through additional studies, which are expensive and time consuming. In some cases, we will not know whether our stability studies are successful until the end of the period for which we are attempting to establish the shelf life. If sufficient shelf life cannot be demonstrated, the products may not achieve customer acceptance and may not receive regulatory approval in the United States.

We will need to develop and test additional configurations of our pathogen inactivation systems 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 compatible with random donor platelets. In order to develop a platelet pathogen inactivation system compatible with random donor platelets, we will need 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 objective that platelets collected on certain future Haemonetics apheresis collection equipment may be directly treated using our platelet system. Baxter and we also are 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.

Fresh frozen plasma and red blood cells are also collected by different methods and equipment and in different volumes. Our systems for plasma and red blood cells being developed and tested will not be suitable for all methods, equipment and volumes used to collect these blood components. We will need to develop and test additional configurations of these systems in order to address the entire market.

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 cause injury, illness or death. We maintain product liability insurance, but do not know whether the insurance will 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 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 $49.4 million in 2001, $57.2 million in 2002 and $58.3 million in 2003. As of December 31, 2003, we had an accumulated deficit of approximately $288.6 million. Except for the INTERCEPT Blood System for platelets, which has received CE Mark approval, all of our products are in the research and development stage, and we have not received significant revenue from product sales. We have received substantially all of our revenue from our agreements with Baxter and other development partners 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 do not generate sufficient cash flow through product sales revenue or by raising additional capital, then we may not be able to meet our debt obligation in 2008.

In January 2003, we received a $50.0 million loan from Baxter Capital Corporation. The interest rate on the loan is 12% per annum. Under the terms of the loan, no payment of principal or interest is due until January 2008. The loan is secured by our present and future accounts receivable from sales of the INTERCEPT Blood System for platelets. Baxter Capital has commenced legal proceedings against us seeking immediate repayment of amounts outstanding under the loan, which would be $56.4 million as of December 31, 2003 if we were in default on the loan. As a result of this action, revenue sharing payments due to us from Baxter are being remitted to Baxter Capital on our behalf and we do not expect to receive further revenue sharing payments from sales of our platelet system unless and until the dispute with Baxter Capital is resolved. Our substantial indebtedness will result in a significant amount of interest expense in future periods. Our indebtedness could have significant additional negative consequences, including limiting our ability to obtain additional financing and to plan for, or react to, changes in our business and the industry in which we compete. If we are unable to satisfy our debt obligation, substantial liquidity problems could result, which would negatively impact our future prospects.

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 product revenue, funding from Baxter and the United States government and projected interest income, will support our current and planned operations until at least December 31, 2005. Our cash, liquidity and capital requirements will depend on many factors, including the development progress and costs of our programs, payments by Baxter and the United States government, costs related to creating, maintaining and defending our intellectual property position, regulatory approval and successful commercialization of our product candidates, competitive developments and regulatory factors.

We expect to require substantial additional funds for our long-term product development, marketing programs and operating expenses. In October 2003, Baxter Capital Corporation commenced legal proceedings against us seeking immediate repayment of principal and interest outstanding under the loan. Principal and interest totaling $55.8 million is outstanding as of December 31, 2003; however if the loan is in default, then, under the terms of the loan agreement, $56.4 million of principal and interest would be due as of December 31, 2003. Baxter Capital alleges that changes in our business constitute a default under the loan agreement. We do not agree that any default has occurred. If we are unsuccessful in defending this legal action, or if we agree to repay all or part of the loan before January 2008, then we will require substantially greater funds to support our operations than currently anticipated. We do not know if we will be able to raise additional funds on acceptable terms. If we are unable to obtain sufficient additional capital, we may need to delay or cease certain development programs. If we raise additional funds by issuing equity securities, our existing stockholders may experience substantial dilution.

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 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, 2003, we owned 67 issued or allowed United States patents and 60 issued or allowed foreign patents. Our patents expire at various dates between 2009 and 2018. In addition, we have 27 pending United States patent applications and have filed 20 corresponding patent applications under the Patent Cooperation Treaty, which are currently pending in Europe, Japan, Australia and Canada, and of which eight are also pending in China and six of which are also pending in 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 12 United States patents relating to vaccines, as well as related foreign patents. 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 United States patent issued to a third-party covers 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 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 viruses. 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 from January 1, 2002 to December 31, 2003, the closing sale price of our common stock as quoted on the Nasdaq National Market fluctuated from a low of $3.40 to a high of $58.68. 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;
- status of development partnerships;
- 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.

If there is an adverse outcome in the securities class action litigation that has been filed against us, our business may be harmed.

We and certain of our officers and directors are named as defendants in a purported securities class action lawsuit filed in the United States District Court for the Northern District of California. The lawsuit is brought on behalf of a purported class of purchasers of our securities, and seeks unspecified damages. As is typical in this type of litigation, another purported securities class action lawsuit containing substantially similar allegations has since been filed against the defendants, and additional lawsuits containing substantially similar allegations may be filed. We expect that all of the substantially similar securities class actions will be consolidated into a single action. In addition, our directors and certain of our officers have been named as defendants in a derivative lawsuit in the Superior Court for the County of Contra Costa, which names Cerus as a nominal defendant. The plaintiff in this action is a Cerus stockholder who seeks to bring derivative claims on behalf of Cerus against the defendants. The lawsuit alleges breaches of fiduciary duty and related claims.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with these lawsuits. In the event of an adverse outcome, our business could be harmed.

Item 2. *Properties*

We lease approximately 21,400 square feet for our main office facility in Concord, California. The lease of the main facility extends through August 2007, with an option to renew for an additional three-year period. We also have leases for approximately 17,400 square feet, approximately 9,900 square feet and approximately 31,808 square feet at three facilities, all of which contain laboratory and office space and are located near our main building in Concord. These leases extend through June 2009, January 2005 and October 2006 (with five one-year renewal options and an option for us to terminate the lease with nine month's notice any time after July 2004), respectively. We have a lease for approximately 11,300 square feet of office space in a facility located near our main building in Concord. This lease extends through August 31, 2004, with two one-year renewal options. We believe that our current facilities and available additional space will be adequate for the foreseeable future.

Item 3. *Legal Proceedings*

On October 14, 2003, Baxter Capital Corporation, a financial subsidiary of Baxter International Inc., filed a complaint in the Circuit Court of Cook County, Illinois against us seeking immediate repayment of amounts outstanding under a loan, which would be $56.4 million as of December 31, 2003 if we were in default on the loan. Baxter Capital alleges that changes in our business constitute a default under the loan agreement. We do not agree that any default has occurred. If we are unsuccessful in defending this legal action, or if we agree to repay all or part of the loan before January 2008, then we will require substantially greater funds from other sources than currently anticipated to support our operations.

On December 8, 2003, a class action complaint was filed in the United States District Court for the Northern District of California against us and certain of our officers and directors. The complaint alleges that the defendants violated the federal securities laws by making certain alleged false and misleading statements. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our securities during the period from October 25, 2000 through September 3, 2003. As is typical in this type of litigation, several other purported securities class action lawsuits containing substantially similar allegations have since been filed against the defendants, and we expect that additional lawsuits containing substantially similar allegations may be filed in the near future. We expect that all of the substantially similar securities class actions will be consolidated into a single action.

On December 15 2003, our directors and certain of our officers were named as defendants in a derivative lawsuit. This action was filed in the Superior Court for the County of Contra Costa and names us as a nominal defendant. The plaintiff in this action is a Cerus stockholder who seeks to bring derivative claims on behalf of Cerus against the defendants. The lawsuit alleges breach of fiduciary duty and related claims.

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

None.

PART II

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

Our 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, 2002:		
First Quarter	53.99	43.50
Second Quarter	59.69	29.79
Third Quarter	33.88	14.79
Fourth Quarter	25.00	11.38
Year Ended December 31, 2003:		
First Quarter	21.75	5.29
Second Quarter	13.20	7.23
Third Quarter	8.23	4.55
Fourth Quarter	5.49	3.40

On February 29, 2004, the last reported sale price of our common stock on the Nasdaq National Market was $3.88 per share. On February 29, 2004, we had approximately 145 holders of record of common stock.

We have not paid dividends on our common stock and do not intend to pay cash dividends on our 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, 2003. 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,				
2003	2002	2001	2000	1999

	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 9,665	$ 8,490	$ 4,535	$ 1,851	$ 2,408
Operating expenses:					
Research and development	52,484	56,421	48,247	34,823	22,514
General and administrative	11,016	11,346	10,166	7,160	4,837
Total operating expenses	63,500	67,767	58,413	41,983	27,351
Loss from operations	(53,835)	(59,277)	(53,878)	(40,132)	(24,943)
Net interest income (expense)	(4,432)	2,085	4,611	4,099	2,315
Loss before income taxes	(58,267)	(57,192)	(49,267)	(36,033)	(22,628)
Provision for income taxes	—	—	(100)	—	—
Net loss	$ (58,267)	$ (57,192)	$ (49,367)	$ (36,033)	$ (22,628)
Net loss per share-basic and diluted(1)	$ (3.01)	$ (3.61)	$ (3.27)	$ (2.75)	$ (2.04)
Shares used in computing net loss per share-basic and diluted(1)	19,367	15,833	15,105	13,086	11,102

	As of December 31,				
	2003	2002	2001	2000	1999
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 110,010	$ 64,318	$ 123,461	$ 90,260	$ 40,419
Working capital	49,819	50,486	108,606	78,884	31,951
Total assets	118,463	72,947	128,260	94,161	41,780
Loan and interest payable to a related party	55,834	—	—	—	—
Capital lease obligations, less current portion	—	16	51	84	115
Redeemable convertible preferred stock	—	—	5,000	5,000	5,000
Accumulated deficit	(288,554)	(230,287)	(173,095)	(123,728)	(87,518)
Total stockholders' equity	52,528	56,169	106,755	76,921	27,959

(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 our financial condition and results of operations should be read in conjunction with our 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 our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development and clinical testing of medical systems based on our Helinx technology. We have been unprofitable since inception and, as of December 31, 2003, had an accumulated deficit of approximately $288.6 million. Except for the INTERCEPT Blood System for platelets, which is approved for sale in Europe, all of our product candidates are in the research and development stage, and we have not received significant revenue to date from product sales. We must conduct significant research, development, pre-clinical and clinical evaluation, commercialization 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 of additional products. Our ability to achieve a profitable level of operations in the

future will depend on our ability to successfully complete development and obtain additional regulatory approvals and on Baxter's ability to commercialize and achieve market acceptance of the INTERCEPT Blood System. We may never achieve a profitable level of operations. Further, under the agreements discussed below, Baxter provides significant funding for development of the INTERCEPT Blood System, based on an annual budgeting process, and is responsible for manufacturing and marketing the products following regulatory approvals. These agreements may be modified or terminated.

Critical Accounting Policies and Management Estimates

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates including those related to collaborative arrangements, contract research and other contingencies. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. 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.

We believe the following critical accounting policies, which have been reviewed by our Audit Committee, 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. We receive certain United States government grants that support our 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—We consider 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. We have classified all debt securities as available-for-sale at the time of purchase and reevaluate such designation as of each balance sheet date. The cost of securities sold is based on the specific identification method.

- Accrued liabilities—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.

- Loan and interest payable to a related party—Baxter Capital has commenced legal proceedings against us seeking immediate repayment of amounts outstanding under a loan to us. We do not agree with Baxter Capital's allegation that a default has occurred and therefore believe that under the terms of the loan, no principal or interest payments are due until January 2008. We have recorded interest expense based on a 12% per annum interest rate. If we are unsuccessful in defending the action by Baxter Capital, then we could be liable for additional interest and penalties. Due to the uncertainty of the outcome of the loan dispute with Baxter Capital, we have classified the loan and accrued interest balance as a current liability. Baxter Capital has instructed Baxter to remit to Baxter Capital payments owing to us for revenue sharing on platelet product sales. We have accounted for amounts paid to Baxter Capital by Baxter on our behalf as a reduction of the loan principal balance.

Collaborations

Agreement with Baxter for the Development of the INTERCEPT Blood System for Platelets. We have a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Blood System for inactivation of viruses, bacteria and other infectious pathogens in platelets used for transfusion. This agreement provides for Baxter and us to generally share system development costs equally, subject to mutually determined budgets established from time to time, and for us 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 is responsible for manufacturing and marketing the INTERCEPT Blood System for platelets. This agreement expires in December 2008 and provides for both parties to make good faith efforts to negotiate one or more three-year renewals unless either party provides written notice of termination no later than 12 months prior to the expiration date.

Agreement with Baxter for the Development of the INTERCEPT Blood System for Red Blood Cells and INTERCEPT Blood System for Plasma. We also have a development and commercialization agreement with Baxter for the joint development of the INTERCEPT Blood System to inactivate viruses, bacteria and other infectious pathogens in red blood cells and fresh frozen plasma for transfusion. This agreement

provides for Baxter and us generally to share red blood cell system development costs equally, subject to mutually determined budgets established from time to time. We are solely responsible for funding the development costs of the INTERCEPT Blood System for plasma. Baxter has an exclusive, worldwide distribution license and will be responsible for manufacturing and marketing the INTERCEPT Blood System for red blood cells and INTERCEPT Blood System for plasma following regulatory approvals. The agreement also provides for an equal sharing of revenue from sales of red blood cell system disposables, and for us to receive 75% and Baxter to receive 25% of revenue from sales of plasma system disposables, in each case after each party is reimbursed for its cost of goods and a specified percentage, not to exceed 14% of revenue, is retained by Baxter for marketing and administrative expenses. The termination of Phase III clinical trials of the red blood cell system does not affect the terms of the agreement and is not expected to affect current sources of

development funding revenue, but will significantly delay the development of, and any potential revenue from, sales of the red blood cell system.

Funding from Baxter. As of December 31, 2003, we have 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, have received proceeds from a $50.0 million loan from Baxter Capital and have recognized approximately $30.4 million in milestone and development funding revenue from Baxter, since inception. Baxter has advised us that Baxter International Inc. and Subsidiaries Pension Trust is not an affiliate of Baxter. Baxter Capital has commenced legal proceedings against us seeking immediate repayment of amounts outstanding under the loan. Baxter Capital alleges that changes in our business constitute a default under the terms of the loan.

Cooperative Agreement with the Armed Forces of the United States. In February 2001, we were awarded a $3.5 million cooperative agreement by the Army Medical Research Acquisition Activity division of the Department of Defense. In September 2002 and May 2003, we were awarded additional $6.5 million and $6.2 million cooperative agreements, respectively, both of which were awarded to continue funding of projects to develop our 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 agreements, we are conducting research on the inactivation of infectious pathogens, including unusual viruses, bacteria and parasites, which are of particular concern to the Armed Forces. We are collaborating with investigators at Walter Reed Army Institute of Research to 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, and a portion of the funding we receive is used by us to fund this research.

Agreement with Kirin. In January 2001, we entered into a collaborative agreement with the Pharmaceutical Division of Kirin to develop and market products for stem cell transplantation based on our Helinx technology. Under the terms of the agreement, we will jointly develop the products with Kirin. We received an initial license fee of $1 million. The license fee is being deferred and recognized as development funding ratably over the development period. We may not receive additional funding from Kirin. Although the agreement calls for Kirin to fund all development expenses for the Asia-Pacific region and a portion of our development activities aimed at obtaining product approval in the United States, no such development activities co-funded by Kirin are currently ongoing. Upon product approval, Kirin has exclusive rights to market the products in the Asia-Pacific region, including Japan, China, Korea and Australia, and we will receive a specified share of product revenue, including a royalty and reimbursement of our cost of goods. We retain all marketing rights for the rest of the world, including the United States and Europe.

Agreement with the National Marrow Donor Program. In October 2001, we entered into an agreement with the National Marrow Donor Program, or NMDP, a non-profit corporation, under which the NMDP sponsors a clinical trial of our allogeneic cellular immune therapy in patients receiving matched unrelated bone marrow transplants. The agreement was amended in December 2002. Under the amended agreement, we provide our Helinx compound amotosalen, illumination devices, training of clinical sites and program oversight in exchange for reimbursement by the NMDP of our related costs. We recognized $481,000 in development funding from the NMDP in the year ended December 31, 2003. The amended agreement expires on March 31, 2004.

Results of Operations

2003 Compared with 2002

Revenue. For the year ended December 31, 2003, milestone and development funding from related parties decreased to $0.4 million from $5.0 million for 2002. Amounts recognized in 2003 were from Baxter for development of the INTERCEPT Blood System for platelets, whereas in 2002 a

$5.0 million milestone payment from Baxter was earned upon regulatory approval of the INTERCEPT Blood System for platelets in Europe. Development funding is in the form of balancing payments made by Baxter to us, if necessary, to reimburse us for development spending in

excess of the levels determined by Baxter and us. In 2004, we expect to recognize development funding totaling less than $1.0 million from Baxter for both the platelet and red blood cell programs. Development funding from Baxter was 4% of total revenue for 2003.

Development funding from other sources, which includes Kirin and the NMDP, decreased 16% to $0.6 million for 2003 from $0.7 million for 2002. Revenue recognized from Kirin in 2003 was from the up-front payment that was deferred and recognized ratably over the development period. There is no development activity co-funded by Kirin currently ongoing or planned at Cerus. The current agreement with the NMDP expires on March 31, 2004. If the agreement with the NMDP is renewed, development funding to Cerus, if any, may be less than under the existing agreement. Development funding from the NMDP was 5% of total revenue for 2003. Development funding from Kirin was 1% of total revenue for 2003.

Revenue from government grants and cooperative agreements increased 214% to $8.6 million for 2003 from $2.7 million for 2002. The increase was principally due to a $5.7 million increase in program expenditures under the cooperative agreements with the Armed Forces of the United States, most of this increase supporting research and development applicable to the INTERCEPT Blood System. During 2003, we also recognized $0.4 million of revenue from six separate research grants from the National Institutes of Health. Two of these grants expired in 2003 and the rest expire in 2004. We may not receive additional government grants in the future.

We recognized $52,000 and $3,000 of product sales revenue in 2003 and 2002, respectively, from sales of the INTERCEPT Blood System for platelets in Europe. As a result of the loan dispute with Baxter Capital, recognition of product sales revenue in the amount of $39,000 for the fourth quarter of 2003 has been deferred until payment of such revenue is expected to be collected. We do not expect to recognize any further product sales revenue until the loan dispute with Baxter Capital is resolved and we cannot predict when this will occur. The INTERCEPT Blood System for platelets is currently undergoing validation studies and regulatory reimbursement review in many European countries. We do not expect sales of the system in Europe to be significant at least until the system is approved for sale and reimbursement in the larger-market European countries. We expect that underlying product sales of the INTERCEPT Blood System for platelets in Europe in 2004 will continue to increase; however, we do not expect potential product sales revenue in 2004, if recognizable, to be sufficient for us to achieve a level of profitable operations.

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 decreased 7% to $52.5 million for 2003 from $56.4 million for 2002. The decrease was due primarily to reduced development spending at Baxter and also to the termination of Phase III clinical trials in the red blood cell program in September 2003. Our total research and development costs included $45.6 million for the INTERCEPT Blood System program and $6.9 million for all other programs for 2003, and $48.7 million for the INTERCEPT Blood System program and $7.7 million for all other programs for 2002. We anticipate that our research and development expenses will decrease primarily as a result of the restructuring of our operations relating to the termination of red blood cell system Phase III clinical trials, which included a reduction in workforce of approximately 25% in October 2003. Ongoing expenses relating to the termination of the red blood cell Phase III clinical trials will be recognized as incurred in 2004 and will be significantly lower than expenses in 2003. In the longer term, we anticipate that our research and development expenses may increase if an additional United States clinical trial of the INTERCEPT Blood System for platelets is conducted, and as development is completed for the

INTERCEPT Blood System for plasma and research and development activity relating to other clinical and 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 costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects; see "Risk Factors" above.

General and Administrative Expenses. General and administrative expenses decreased 3% to $11.0 million for 2003 from $11.3 million for 2002. The slight decrease was principally attributable to fewer administrative personnel and consultants in 2003. We expect our general and administrative expenses to decrease slightly in 2004 as a result of our restructuring, due to the reduction in workforce in October 2003. In the longer term, we expect our general and administrative expenses to increase moderately as development and commercialization activities progress.

Net Interest Income (Expense). Net interest expense was $4.4 million for 2003 compared to net interest income of $2.1 million for 2002. We received proceeds from a $50.0 million loan from Baxter Capital in January 2003 and recorded $5.9 million of related interest expense in 2003. Interest income from investments was $1.5 million for 2003 compared to $2.1 million for 2002. The decrease was primarily due to reduced yields on investments as a result of declines in market interest rates. We expect to earn interest at market rates in proportion to the balances we maintain.

2002 Compared with 2001

Revenue. For the year ended December 31, 2002, milestone and development funding from Baxter and the Consortium increased to

$5.0 million from $2.1 million for 2001. The increase was due to a $5.0 million milestone payment from Baxter earned in 2002 upon regulatory approval of the INTERCEPT Blood System for platelets in Europe. Development funding from Baxter was 59% of total revenue for 2002. Development funding from the Consortium was less than 1% of total revenue for 2002.

Development funding from other sources, which includes Kirin and the NMDP, decreased 25% to $0.7 million for 2002 from $1.0 million for 2001. The decrease was due to a $0.7 million decrease in development funding from Kirin in 2002. Development funding from the NMDP was 6% of total revenue for 2002. Development funding from Kirin was 2% of total revenue for 2002.

Revenue from government grants and cooperative agreements increased 90% to $2.7 million for 2002 from $1.4 million for 2001. The increase was principally due to a $1.4 million increase in program expenditures under the cooperative agreements with the Armed Forces of the United States that were entered into in February 2001 and September 2002. During 2002, we also recognized revenue under a grant from the National Institutes of Health that expired in July 2002.

We recognized $3,000 of product sales revenue in 2002 from sales of the INTERCEPT Blood System for platelets in Europe.

Research and Development Expenses. Research and development expenses increased 17% to $56.4 million for 2002 from $48.2 million for 2001. The increase was due primarily to the addition of scientific personnel, increased facilities costs and increased development spending at Baxter. Our total research and development costs incurred included $48.7 million for the INTERCEPT Blood System program and $7.7 million for all other programs for 2002, and $40.5 million for the INTERCEPT Blood System program and $7.8 million for all other programs for 2001.

General and Administrative Expenses. General and administrative expenses increased 12% to $11.3 million for 2002 from $10.2 million for 2001. The increase was principally attributable to the

addition of administrative personnel, increased costs for insurance and increased facilities expenses associated with expansion of our operations.

Net Interest Income. Net interest income decreased 55% to $2.1 million for 2002 from $4.6 million for 2001. The decrease was primarily due to reduced investment balances carried in 2002 and less favorable yields on investments as a result of declining interest rates.

Liquidity and Capital Resources

Our sources of capital to date have primarily consisted of public offerings and private placements of equity securities, the loan from Baxter Capital, payments received under our agreements with Baxter, Kirin, the NMDP and the Consortium, United States government grants and cooperative agreements and interest income. To date, we have not received significant revenue from product sales, and we will not derive significant revenue from product sales unless and until one or more products receive regulatory approval and achieve market acceptance. As a result of the loan dispute with Baxter Capital, recognition of product sales revenue in the amount of $39,000 for the fourth quarter of 2003 has been deferred. We do not expect to recognize any further product sales revenue until the loan dispute with Baxter Capital is resolved and we cannot predict when this will occur.

At December 31, 2003, we had cash, cash equivalents and short-term investments of $110.0 million. Net cash used in operating activities was $58.6 million in 2003, compared to $55.7 million in 2002. The use of cash primarily resulted from a net loss of $58.3 million and changes in other operating balances, including accrued interest of $5.9 million. Net cash used in investing activities in 2003 of $45.2 million resulted principally from the purchases of $191.7 million of short-term investments and the purchase of $0.3 million of furniture and equipment, offset by the sales and maturities of $146.7 million of short-term investments. Working capital decreased to $49.8 million at December 31, 2003 from $50.5 million at December 31, 2002, primarily due to $58.6 million of net cash used in operating activities for 2003 and the classification of $55.8 million of loan and accrued interest payable to Baxter Capital as current liabilities as of December 31, 2003 due to uncertainty as to the potential outcome of legal proceedings, partially offset by net proceeds of $50.0 million from the loan in January 2003 and $54.1 million from the public offering of common stock in June 2003.

We believe that our available cash balances, together with anticipated cash flows from existing development and grant arrangements, will be sufficient to meet our capital requirements until at least December 31, 2005 irrespective of the timing of repayment of any amounts due under the loan from Baxter Capital. These near-term capital requirements are dependent on various factors, including the development progress and costs of the INTERCEPT Blood System and other programs; payments to or from Baxter and the United States government; and costs related to creating, maintaining and defending our intellectual property position. Our long-term capital requirements will be dependent on these factors and on the outcome of the loan dispute with Baxter Capital whereby Baxter Capital is seeking immediate repayment of outstanding principal, interest and default penalties totaling $56.4 million as of December 31, 2003, the outcome of ongoing securities class action and derivative lawsuits against us, our ability to raise capital through public or private equity or debt financings or through additional collaborative arrangements or government grants, regulatory approval and successful commercialization of the INTERCEPT Blood System and other product candidates, competitive developments and regulatory factors. If Baxter were to terminate its agreements with us, we might not be able

to meet our long-term capital requirements. Future capital funding transactions may result in dilution to our investors, and may not be available on favorable terms or at all. In August 2001, we filed a shelf registration statement on Form S-3 to offer and sell up to $300 million of common stock and/or debt securities. In June 2003, we completed a public offering of 6,000,000 shares of common stock with gross proceeds, calculated for registration statement purposes, of $57.8 million under the shelf registration statement. We have no current commitments to offer or sell additional securities pursuant to this registration statement.

Commitments

Our commitments are as follows:

	Payments Due by Period from December 31, 2003				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
	(in thousands)				
Contractual obligations:					
Loan and interest payable to a related party	$ 55,834	$ 55,834	$ —	$ —	$ —
Minimum purchase requirements	200	50	100	50	—
Capital lease obligations	20	20	—	—	—
Operating leases	3,706	1,393	1,324	539	450
Total contractual cash obligations	$ 59,760	$ 57,297	$ 1,424	$ 589	$ 450

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

We maintain 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, 2003 and 2002 were not material. Our investments primarily consist of short-term money market mutual funds, United States government obligations and commercial paper. We do not believe our exposure to interest rate risk to be material given the short-term nature of our investment portfolio. The table below presents the amortized principal amount, which approximates fair value, and related weighted average interest rates for our investment portfolio at December 31, 2003:

	Amortized Principal Amount	Weighted Average Interest Rate
	(in thousands)	
Cash equivalents	$ 18,379	1.08%
Short-term investments (91 days-1 year)	15,255	1.41%
Short-term investments (1-2 years)	71,589	1.65%
Total investments	$ 105,223	

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

Our financial statements, together with related notes and report of Ernst & Young LLP, independent auditors, are listed in Item 15(a) and included herein.

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

Not applicable.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures. Our chief executive officer and chief financial officer are responsible for establishing and maintaining "disclosure controls and procedures" (as defined in rules promulgated under the Securities Exchange Act of 1934, as amended) for our company. Based on their evaluation of our disclosure controls and procedures as of December 31, 2003, our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2003.

Changes in Internal Controls over Financial Reporting. There were no significant changes in our internal control over financial reporting during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and the chief executive officer and the chief financial officer have concluded that these controls and procedures are effective at the "reasonable assurance" level.

PART III

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

Information regarding our directors and officers, and the compliance of certain reporting persons with Section 16(a) of the Securities Exchange Act of 1934, as amended, will be set forth under the captions "Election of Directors," "Management," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Code of Ethics" in our definitive proxy statement for use in connection with the annual meeting of stockholders to be held on June 11, 2004 (the "Proxy Statement") and is incorporated herein by reference. We intend to file the Proxy Statement with the Securities and Exchange Commission within 120 days after the end of our 2003 fiscal year.

Item 11. ***Executive Compensation***

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

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

The information required by this item is incorporated herein by reference to the information set forth under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in the Proxy Statement.

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

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

Item 14. ***Principal Accountant Fees and Services***

The information required by this item is incorporated herein by reference to the information set forth under the captions "Independent Auditors' Fees" and "Policy on Audit Committee Pre-Approval" in the Proxy Statement.

PART IV

Item 15. ***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.*

	Page
Report of Ernst & Young LLP, Independent Auditors	52
Balance Sheets as of December 31, 2003 and 2002	53
Statements of Operations for the three years ended December 31, 2003	54
Statements of Stockholders' Equity for the three years ended December 31, 2003	55
Statements of Cash Flows for the three years ended December 31, 2003	56
Notes to Financial Statements	57

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

(b) *Reports on Form 8-K*

On October 16, 2003, the Company filed a report on Form 8-K that included as exhibits the press release announcing that it is restructuring its operations to focus on its pathogen inactivation products for platelets and plasma and on its pipeline of therapeutics and vaccines and the press release announcing that Baxter Capital Corporation, a financial subsidiary of Baxter International Inc., commenced legal proceedings against the Company seeking repayment of amounts outstanding under a credit facility it provided to the Company.

On October 30, 2003, the Company filed a report on Form 8-K that included as an exhibit the press release announcing its third quarter 2003 financial results.

On December 10, 2003, the Company filed a report on Form 8-K disclosing that on December 8, 2003, a class action complaint was filed against the Company and certain of its directors and officers. The complaint alleges that the defendants violated federal securities laws by making certain alleged false and misleading statements. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of the Company's securities.

(c) *Exhibits*

Exhibit Number	Description of Exhibit
3.1.1(5)	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†(10)	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 Cerus 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†(2)	License Agreement, dated as of November 30, 1992, by and among the Company, Miles Inc. and Diamond Scientific Corporation.
10.28†(3)	Amendment to Development, Manufacturing and Marketing Agreement, dated as of March 6, 1998, by and between Cerus and Baxter Healthcare Corporation.
10.29(4)	Series A Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation.
10.30(4)	Series B Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation.
10.31(4)	Memorandum of Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation.
10.32(10)	Second Amendment to Development, Manufacturing and Marketing Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation.
10.33†(4)	Development, Manufacturing and Marketing Agreement, dated April 1, 1996, by and between Cerus and Baxter Healthcare Corporation, as amended and restated June 30, 1998.
10.34(5)	Stockholder Rights Plan, dated November 3, 1999.
10.35(6)*	1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999
10.36(7)*	Employment Agreement with Howard G. Ervin.
10.37†(8)	Collaborative License Agreement between Cerus and Kirin Brewery Company, Limited.
10.38(9)	Amendment to Section 4.2 of the June 30, 1998 Development Agreement between Cerus and Baxter.
10.39(11)	Lease, dated December 17, 1999 between Cerus and Redwoods Office Center, L.P.
10.40(11)	Lease, dated October 12, 2001 between Cerus and California Development, Inc.
10.41(12)	Loan Agreement, dated November 15, 2002, between Cerus and Baxter Capital Corporation.
10.42†(12)	Letter of Understanding between Cerus and Baxter, dated November 1, 2002.
10.43(13)*	1999 Non-Employee Directors' Stock Option Sub-Plan, amended December 4, 2002.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney (see signature page).
31.1	Certification of the Chief Executive Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2	Certification of the Chief Financial Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

† 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' Annual Report on Form 10-K, for the year ended December 31, 1997.

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

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

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

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

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

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

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

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

(11) Incorporated by reference to Cerus' Annual Report on Form 10-K, for the year ended December 31, 2001.

(12) Incorporated by reference to Cerus' Annual Report on Form 10-K, for the year ended December 31, 2002.

(13) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2003.

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, 2003 and 2002, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2003. 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, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
January 23, 2004

CERUS CORPORATION

BALANCE SHEETS

(in thousands, except share and per share data)

	December 31,	
	2003	2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,165	$ 22,435
Short-term investments	86,845	41,883
Accounts receivable from related parties	8	46
Accounts receivable and other current assets	5,736	2,884
Total current assets	115,754	67,248
Furniture and equipment at cost:		
Laboratory and office equipment	5,578	5,353

Leasehold improvements	7,300	7,295
	12,878	12,648
Less accumulated depreciation and amortization	10,325	7,101
Net furniture and equipment	2,253	5,547
Other assets	156	152
Total assets	$ 118,463	$ 72,947
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable to a related party	$ 3,156	$ 8,538
Loan and interest payable to a related party	55,834	—
Accounts payable	1,487	2,022
Accrued compensation and related expenses	2,075	2,476
Accrued contract research expenses	1,200	1,554
Other accrued expenses	1,550	1,419
Deferred revenue	614	718
Current portion of capital lease obligations	19	35
Total current liabilities	65,935	16,762
Capital lease obligations, less current portion	—	16
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value: issuable in series; 3,327 shares issued and outstanding at December 31, 2003 and 2002; aggregate liquidation preference of $9,496 at December 31, 2003 and 2002	9,496	9,496
Common stock, $0.001 par value; 50,000,000 shares authorized: 22,060,249 and 15,949,663 shares issued and outstanding at December 31, 2003 and 2002, respectively	22	16
Additional paid-in capital	331,564	276,944
Accumulated deficit	(288,554)	(230,287)
Total stockholders' equity	52,528	56,169
Total liabilities and stockholders' equity	$ 118,463	$ 72,947

See accompanying notes.

CERUS CORPORATION

STATEMENTS OF OPERATIONS

(in thousands, except share and per share data)

	Years ended December 31,		
	2003	2002	2001
Revenue:			
Milestone and development funding, related parties	$ 398	$ 5,002	$ 2,103
Development funding, other	624	747	993
Government grants and cooperative agreements	8,591	2,738	1,439
Product sales	52	3	—

Total revenue	9,665	8,490	4,535
Operating expenses:			
Research and development	52,484	56,421	48,247
General and administrative	11,016	11,346	10,166
Total operating expenses	63,500	67,767	58,413
Loss from operations	(53,835)	(59,277)	(53,878)
Interest income (expense):			
Interest income	1,472	2,095	4,626
Interest expense	(5,904)	(10)	(15)
Net interest income (expense)	(4,432)	2,085	4,611
Loss before income taxes	(58,267)	(57,192)	(49,267)
Provision for income taxes	—	—	(100)
Net loss	$ (58,267)	$ (57,192)	$ (49,367)
Net loss per share—basic and diluted	$ (3.01)	$ (3.61)	$ (3.27)
Shares used in computing net loss per share—basic and diluted	19,366,727	15,833,403	15,105,003

See accompanying notes.

CERUS CORPORATION

STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share data)

	Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
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
Conversion of Series A preferred stock to common stock	—	—	129,968	—	5,000	—	5,000
Issuance of common stock for services	—	—	1,000	—	33	—	33
Issuance of common stock under stock option and employee stock purchase plans	—	—	81,530	—	1,573	—	1,573
Net loss	—	—	—	—	—	(57,192)	(57,192)
Balances at December 31, 2002	3,327	9,496	15,949,663	16	276,944	(230,287)	56,169
Issuance of common stock, net of							

expenses of $236	—	—	6,000,000	6	54,058	—	54,064
Issuance of common stock under stock option and employee stock purchase plans	—	—	110,586	—	562	—	562
Net loss	—	—	—	—	—	(58,267)	(58,267)
Balances at December 31, 2003	3,327	$ 9,496	22,060,249	$ 22	$ 331,564	$ (288,554)	$ 52,528

See accompanying notes.

CERUS CORPORATION

STATEMENTS OF CASH FLOWS

(in thousands)

	Years ended December 31,		
	2003	2002	2001
Operating activities			
Net loss	$ (58,267)	$ (57,192)	$ (49,367)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,291	2,497	1,193
Issuance of common stock for services	—	33	756
Gain on sale of equipment	(10)	—	—
Changes in operating assets and liabilities:			
Accounts receivable from a related party	(25)	(20)	241
Other current assets	(2,852)	(1,311)	(1,061)
Other assets	(4)	36	(60)
Accounts payable to a related party	(5,382)	3,509	3,238
Accrued interest payable to a related party	5,897	—	—
Accounts payable	(535)	(1,198)	(1,059)
Accrued compensation and related expenses	(401)	(158)	673
Accrued contract research expenses	(354)	(1,242)	455
Other accrued expenses	131	(398)	64
Deferred revenue	(104)	(209)	927
Net cash used in operating activities	(58,615)	(55,653)	(44,000)
Investing activities			
Purchases of furniture and equipment	(297)	(5,032)	(1,236)
Proceeds from sale of equipment	10	—	25
Purchases of short-term investments	(191,695)	(100,157)	(78,892)
Sale of short-term investments	83,089	53,033	11,000
Maturities of short-term investments	63,644	64,199	27,323
Net cash provided by (used in) investing activities	(45,249)	12,043	(41,780)
Financing activities			
Net proceeds from issuance of common stock	54,626	1,573	78,445
Proceeds from loan payable to a related party	50,000	—	—
Payments on capital lease obligations	(32)	(31)	(33)
Net cash provided by financing activities	104,594	1,542	78,412
Net increase (decrease) in cash and cash equivalents	730	(42,068)	(7,368)
Cash and cash equivalents, beginning of period	22,435	64,503	71,871
Cash and cash equivalents, end of period	$ 23,165	$ 22,435	$ 64,503

Supplemental disclosures:			
Interest paid	$ 7	$ 10	$ 15
Accounts receivable from a related party applied to loan payable to a related party	$ 63	$ —	$ —

See accompanying notes.

CERUS CORPORATION

NOTES TO FINANCIAL STATEMENTS

December 31, 2003

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. The Company's most advanced programs are focused on systems to inactivate viruses, bacteria, other pathogens and white blood cells in blood products intended for transfusion. The Company also is pursuing therapeutic and vaccine applications of its technology to treat and prevent serious diseases. The Company has collaboration agreements with Baxter Healthcare Corporation ("Baxter," a subsidiary of Baxter International Inc.) and the Pharmaceutical Division of Kirin Brewery Co., Ltd. ("Kirin"). The Company has not received material revenue from product sales, and substantially all revenue recognized by the Company to date has resulted from the Company's agreements with Baxter, Kirin and others and federal research grants and collaborative agreements. The Company will be required to conduct significant research, development, testing and regulatory compliance activities on its product candidates 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 additional regulatory approvals and achieving market acceptance of its potential products. 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. The Company records 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 do 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, the National Marrow Donor Program ("NMDP") and the Consortium for Plasma Science ("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. Payments for achieved milestones are non-refundable and are not subject to future performance. During the year ended December 31, 2002, the Company recognized $5,000,000 of milestone revenue from Baxter upon European regulatory approval for the platelet system. There was no revenue recognized related to milestones or other up-front payments during the years ended December 31, 2003 and 2001.

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, other laboratory studies, process development and compound and other manufacturing for research use.

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 2003, the Securities and Exchange Commission published Staff Accounting Bulletin No. 104, "Revenue Recognition" ("SAB 104"). SAB 104 rescinds Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" and provides guidance on the recognition, presentation and disclosure of revenue in financial statements. The Company recognizes revenue in accordance with SAB 104.

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 Company reports the amortization of any discount or premium resulting from the purchase of debt securities as a component of interest income. The available-for-sale securities recorded at amounts that approximate fair value at December 31, 2003 and 2002 totaled $105,223,000 and $64,298,000, respectively.

Unrealized gains and losses at December 31, 2003 and 2002 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 ("APB 25"), including Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation: An Interpretation of APB No. 25," ("FIN 44"), and has

adopted the "disclosure only" alternative described in Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," as amended by Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure" ("FAS 123").

The following table illustrates the effect on net loss and related net loss per share, had compensation expense for stock-based compensation plans been determined based on the fair value method prescribed under FAS 123:

	2003	2002	2001
	(in thousands, except per share data)		
Net loss:			

As reported	$ (58,267)	$ (57,192)	$ (49,367)
Add:			
Stock-based employee compensation expense included in reported net loss, net of related tax effects	—	—	—
Less:			
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	8,300	15,491	12,239
Pro forma	$ (66,567)	$ (72,683)	$ (61,606)
Net loss per share—basic and diluted, as reported	$ (3.01)	$ (3.61)	$ (3.27)
Net loss per share—basic and diluted, pro forma	$ (3.44)	$ (4.59)	$ (4.08)

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 preferred stock and from stock options 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.

Guarantee and Indemnification Arrangements

On January 1, 2003, the Company implemented the provisions of Financial Accounting Standards Board Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" ("FIN 45"). Under FIN 45, the Company recognizes the fair value for guarantee and indemnification arrangements issued or modified by the Company after December 31, 2002, if these arrangements are within the scope of the Interpretation. In addition, the Company monitors the conditions that are subject to the guarantees and indemnifications, as required under previously existing generally accepted accounting principles, in order to identify if a loss has occurred. If the Company determines it is probable that a loss has occurred then any such estimable loss would be recognized under those guarantees and indemnifications. Some of the development arrangements of the Company contain provisions that indemnify the counterparty of the Company's technology from damages and costs resulting from claims alleging that the Company's technology infringes the intellectual property rights of a third party. The Company has not received any such requests for indemnification under these provisions and has not been required to make material payments pursuant to these provisions. Accordingly, the Company has not recorded a liability related to these indemnification provisions. The Company does not have any guarantees or indemnification arrangements other than the indemnification clause in some of its development arrangements. The implementation of the provisions of FIN 45 did not have a material impact on the Company's financial position, results of operations or cash flows.

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 using the Company's proprietary technology for controlling biological replication, and the required disclosures are reflected in the financial statements.

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 periodically, 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 specified amounts. Baxter has an exclusive, worldwide distribution license and is responsible for manufacturing and marketing the system following regulatory approval.

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 plasma 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 periodically. The Company is solely responsible for funding the development costs of the system for plasma. 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 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. The termination of

Phase III clinical trials of the red blood cell system does not affect the terms of the agreement, but will significantly delay the development of, and any potential revenue from, sales of the red blood cell system.

This agreement also provides that Baxter and its affiliates will not acquire capital stock of the Company if the acquisition would result in Baxter and its affiliates owning 5.4% or more 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, 2003, Baxter owned less than 5% of the Company's outstanding common stock.

As of December 31, 2003, 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, has received proceeds from a $50.0 million loan from Baxter Capital Corporation ("Baxter Capital," a financial subsidiary of Baxter International Inc.) and has recognized approximately $30.4 million in revenue from Baxter, since inception. Baxter has advised the Company that Baxter International Inc. and Subsidiaries Pension Trust is not an affiliate of Baxter. Baxter Capital has commenced legal proceedings against the Company seeking immediate repayment of amounts outstanding under the loan. Baxter Capital alleges that changes in the Company's business constitute a default under the terms of the loan (see Note 4). 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 $1.0 million. The license fee is being deferred and recognized as development funding ratably over the term of the agreement. Although the agreement calls for Kirin to 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, no such development activities co-funded by Kirin are currently ongoing or planned and the Company does not expect to receive additional funding from Kirin. Upon product approval, Kirin has exclusive rights to market the products in the Asia-Pacific region, including Japan, China, Korea and Australia, and the Company would receive a specified share of product revenue, including a royalty and reimbursement of our cost of goods. The Company retains all marketing rights in the rest of the world, including the United States and Europe. The Company recognized $143,000, $209,000 and $914,000 in development funding from Kirin during the years ended December 31, 2003, 2002 and 2001, respectively.

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. In September 2002 and May 2003, the Company was awarded additional $6.5 million and $6.2 million cooperative agreements, respectively, both of which were awarded to continue funding of projects 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 agreements, we are conducting research on the inactivation of infectious pathogens, including unusual viruses,

bacteria and parasites, which are of particular concern to the Armed Forces. We are collaborating with investigators at the Walter Reed Army Institute of Research to 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. The Company recognized $8,200,000, $2,526,000 and $1,150,000 of revenue under these agreements during the years ended December 31, 2003, 2002 and 2001, respectively.

Agreement with the National Marrow Donor Program

In October 2001, the Company and the NMDP, a non-profit corporation, entered into an agreement under which the NMDP is sponsoring a clinical trial of our allogeneic cellular immune therapy in patients receiving matched unrelated bone marrow transplants. The agreement was amended in December 2002. Under the amended agreement, the Company will provide its proprietary compound amotosalen, illumination devices, training of clinical sites and program oversight in exchange for reimbursement by the NMDP of the Company's related costs. The Company recognized $481,000, $538,000 and $79,000 in development funding from the NMDP during the years ended December 31, 2003, 2002 and 2001, respectively.

Agreement with the Consortium for Plasma Science, a Related Party of the Company

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. The Company does not expect to receive additional funding from the Consortium. If the Company develops and commercializes a pathogen inactivation system for source plasma for fractionation, a royalty may be owed to the Consortium based on a percentage of the sales of such product. The Company recognized $2,000 and $226,000 in development funding from the Consortium during the years ended December 31, 2002 and 2001, respectively.

3. Investments

Available-for-sale securities are recorded at amounts that approximate fair market value. All securities are classified as current assets because the Company considers these to be available to fund current operations. Realized and unrealized gains and losses at December 31, 2003 and 2002 were not material. Investments classified as available-for-sale were as follows:

	December 31,	
	2003	2002
	(in thousands)	
Money market mutual funds	$ 4,384	$ 6,929
United States and state government obligations	54,099	22,761
Commercial paper and corporate securities	46,740	34,608
Total investments	105,223	64,298
Less: amounts classified as cash equivalents	(18,378)	(22,415)
Short-term investments	$ 86,845	$ 41,883

Of the Company's debt securities at December 31, 2003, securities in the aggregate amount of $18,378,000 have original maturity dates of less than three months, securities in the aggregate amount of $15,255,000 have original maturities of three months to one year and securities in the aggregate amount of $71,589,000 have original maturities of greater than one year.

4. Loan Payable to Baxter Capital Corporation, a Related Party of the Company

In January 2003, the Company received proceeds from a $50.0 million loan from Baxter Capital Corporation ("Baxter Capital"), a

financial subsidiary of Baxter International Inc. separate from Baxter. The interest rate on the loan is 12% per annum. Under the terms of the loan, no payment of principal or interest is due until 2008. The loan is secured by the Company's present and future accounts receivable from sales of the platelet system under the agreement with Baxter.

In October 2003, Baxter Capital commenced legal proceedings against the Company seeking immediate repayment of amounts outstanding under the loan. Baxter Capital alleges that changes in the Company's business constitute a default under the loan agreement. The Company does not agree that any default has occurred and therefore believes that, under the terms of the loan, no principal or interest payments are due until January 2008. Due to uncertainty as to the potential outcome of the legal proceedings, the Company has classified amounts due to Baxter Capital under the loan as a current liability in the balance sheet.

Under the loan agreement, if an event of default occurs, unpaid principal and interest as of the default date will accrue interest at 14% per annum. The Company believes that no default has occurred and has recorded accrued interest totaling $5,897,000 as of December 31, 2003 based on the 12% rate stated in the loan agreement. If the Company is unsuccessful in defending the action by Baxter Capital, then the Company could be liable for additional accrued interest of $465,000 as of December 31, 2003. The Company could also be liable for Baxter Capital's legal fees related to this matter.

In October 2003, Baxter Capital instructed Baxter to remit to Baxter Capital payments owing to the Company for revenue sharing on platelet product sales. Baxter has informed the Company that $24,000, representing the Company's share of revenue from product sales in the third quarter of 2003, was paid to Baxter Capital in November 2003 on the Company's behalf. The Company expects that Baxter will continue to remit to Baxter Capital platelet product revenue sharing payments until the loan dispute with Baxter Capital is resolved. As a result, recognition of product sales revenue in the amount of $39,000 for the fourth quarter of 2003 has been deferred as of December 31, 2003 and amounts representing third and fourth quarter product sales totaling $63,00 have been applied against the loan balance.

5. 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 $142,000 at December 31, 2003 and $173,000 at December 31, 2002.

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

Year ending December 31,	Capital Leases	Operating Leases
	(in thousands)	
2004	$ 20	$ 1,273
2005	—	308
2006	—	300
2007	—	300
2007	—	300
Thereafter	—	150
Total minimum lease payments	20	$ 2,631
Amount representing interest	1	
Present value of net minimum lease payments	$ 19	

Rent expense for office facilities was $1,344,000, $1,219,000 and $900,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

On December 8, 2003, a class action complaint was filed in the United States District Court for the Northern District of California against the Company and certain of its present and former directors and officers. On December 10, 2003, a second action was filed in the same court against the same defendants. Both actions were brought on behalf of a purported class of persons who purchased the Company's publicly traded

securities between October 25, 2000 and September 3, 2003. The complaints alleged that the defendants violated the federal securities laws by making certain alleged false and misleading statements regarding clinical trials of the Company's red blood cell system. In addition, certain of the Company's present and former directors and officers have been named as defendants in a derivative lawsuit in the Superior Court for the County of Contra Costa, which names the Company as a nominal defendant. The plaintiff in this action is a Company stockholder who seeks to bring derivative claims on behalf of the Company against the defendants. The lawsuit alleges breach of fiduciary duty and related claims. The Company cannot predict the outcome of this litigation.

6. Stockholders' Equity

Series A Redeemable Convertible Preferred Stock

Upon regulatory approval of the platelet system in Europe, all 5,000 outstanding shares of Series A preferred stock were converted to common shares in July 2002. The Company issued a total of 129,968 common shares to Baxter, the holder of the Series A preferred stock, in connection with this conversion. The conversion price was based on the average of 120% of the average closing price of the common stock 30 trading days prior to CE Mark approval of the disposable set for the platelet system and 120% of the average closing price of the common stock 30 trading days prior to CE Mark of the illumination device for the platelet system.

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 1.5% of the outstanding common shares of the Company at

December 31, 2003. The Company has the right to redeem the Series B preferred stock prior to conversion for a payment of $9.5 million.

Common Stock

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 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 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.

In August 2001, the Company 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. In June 2003, the Company completed a public offering of 6,000,000 shares of common stock registered under the shelf registration statement and received net proceeds of $54.1 million, after deducting related expenses. The Company currently has no further commitments to offer or sell securities pursuant to this registration statement.

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 4,780,000 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 APB 25 and related interpretations, including FIN 44, 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 or exceeds 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 model with the following weighted-average assumptions for the years ended December 31:

	Stock Option Plans			Employee Stock Purchase Plan		
	2003	2002	2001	2003	2002	2001
Expected volatility	.884	.637	.684	.885	.637	.684
Risk-free interest rate	2.96%	2.80%	3.50%	2.24%	1.50%	3.50%
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.

Activity under the stock option plans is set forth below:

	Number of Options Outstanding	Weighted Average Exercise Price per Share
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
Granted	1,162,871	42.597
Cancelled	(131,408)	43.672
Exercised	(54,084)	17.692
Balances at December 31, 2002	3,159,090	$ 34.703
Granted	1,026,092	5.944
Cancelled	(607,234)	32.353
Exercised	(24,286)	2.682
Balances at December 31, 2003	3,553,662	$ 27.029

The weighted average fair value of options granted during the years ended December 31, 2003, 2002 and 2001 was $3.416, $19.650 and $21.824 per share, respectively. At December 31, 2003, options to purchase 1,983,982 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	127,734	2.27	$ 2.621	127,734	$ 2.621
$ 3.730— 4.250	510,959	9.89	$ 4.250	10,574	$ 4.250
$ 4.680— 7.520	389,688	9.35	$ 7.089	54,777	$ 6.993
$ 7.550—19.500	387,536	5.90	$ 14.540	343,024	$ 14.878
$21.000—21.060	205,319	8.14	$ 21.046	90,848	$ 21.028
$21.061—24.875	370,272	6.05	$ 24.406	363,090	$ 24.401
$26.250—29.290	145,257	6.50	$ 27.199	122,118	$ 27.234
$32.470—38.188	412,879	7.21	$ 37.895	290,454	$ 37.830
$39.063—50.050	257,222	7.60	$ 46.505	172,771	$ 46.097
$50.180—75.250	746,796	7.96	$ 53.873	397,094	$ 55.770
	3,553,662	7.60	$ 27.029	1,972,484	$ 30.956

Employee Stock Purchase Plan

The Company has reserved 320,500 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 86,300, 27,446 and 12,480 shares under the Purchase Plan during the years ended December 31, 2003, 2002 and 2001, respectively. At December 31, 2003, 109,518 shares were available for issuance. The weighted average fair value per share of the rights granted during the years ended December 31, 2003, 2002 and 2001 using the Black-Scholes model was $3.004, $19.357 and $10.636, 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,	
	2003	2002
	(in thousands)	
Net operating loss carryforward	$ 100,100	$ 81,300
Research and development credit carryforward	20,400	13,500
Certain expenses not currently deductible for tax purposes	3,200	3,500
Accrued liabilities	1,200	1,400
Capitalized research and development	5,300	2,300
Other	2,100	1,100
Gross deferred tax assets	132,300	103,100
Valuation allowance	(132,300)	(103,100)
Net deferred tax assets	$ —	$ —

The valuation allowance increased by $29,200,000 and $25,100,000 for the years ended December 31, 2003 and 2002, 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, 2003 includes $2,800,000 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 consisted 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, 2003, the Company had net operating loss carryforwards of approximately $262,700,000 for federal and $180,000,000 for state income tax purposes. The Company also had research and development tax credit carryforwards of approximately $13,900,000 for federal income tax purposes and approximately $9,800,000 for state income tax purposes at December 31, 2003. The federal net operating loss and tax credit carryforwards expire between the years 2007 and 2023. The state net operating loss carryforwards expire between the years 2004 and 2013. The state research and development credits do not expire.

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, 2003, 2002 and 2001.

9. Quarterly Financial Information (Unaudited)

	Three Months Ended			
	March 31, 2003	June 30, 2003	September 30, 2003	December 31, 2003
	(In thousands, except per share data)			
Revenue:				
Milestone and development funding, related parties	$ —	$ —	$ —	$ 398
Development funding, other	169	113	257	85
Government grants and cooperative agreements	1,080	1,882	2,587	3,042
Product sales	20	8	24	—
Total revenue	1,269	2,003	2,868	3,525
Operating expenses:				
Research and development	14,695	14,752	13,400	9,637
General and administrative	2,695	2,823	2,587	2,911
Total operating expenses	17,390	17,575	15,987	12,548
Loss from operations	(16,121)	(15,572)	(13,119)	(9,023)
Net interest expense	(1,038)	(1,200)	(1,089)	(1,105)

Net loss	$ (17,159)	$ (16,772)	$ (14,208)	$ (10,128)
Net loss per share—basic and diluted	$ (1.07)	$ (0.97)	$ (0.64)	$ (0.46)

	Three Months Ended			
	March 31, 2002	June 30, 2002	September 30, 2002	December 31, 2002
	(In thousands, except per share data)			
Revenue:				
Milestone and development funding, related parties	$ 2	$ 5,000	$ —	$ —
Development funding, other	103	36	167	441
Government grants and cooperative agreements	398	613	563	1,164
Product sales	—	—	—	3
Total revenue	503	5,649	730	1,608
Operating expenses:				
Research and development	11,921	14,484	14,881	15,135
General and administrative	2,802	3,024	2,925	2,595
Total operating expenses	14,723	17,508	17,806	17,730
Loss from operations	(14,220)	(11,859)	(17,076)	(16,122)
Net interest income	673	575	485	352
Net loss	$ (13,547)	$ (11,284)	$ (16,591)	$ (15,770)
Net loss per share—basic and diluted	$ (0.86)	$ (0.71)	$ (1.05)	$ (0.99)

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 12th day of March, 2004.

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 Stephen T. Isaacs	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 12, 2004
/s/ GREGORY W. SCHAFER Gregory W. Schafer	Chief Financial Officer and Vice President, Finance *(Principal Financial and Accounting Officer)*	March 12, 2004
/s/ B. J. CASSIN B. J. Cassin	Chairman of the Board	March 12, 2004
/s/ TIMOTHY B. ANDERSON Timothy B. Anderson	Director	March 12, 2004
/s/ LAURENCE M. CORASH, M.D. Laurence M. Corash, M.D.	Director	March 12, 2004
/s/ BRUCE C. COZADD Bruce C. Cozadd	Director	March 12, 2004
/s/ C. RAYMOND LARKIN, JR. C. Raymond Larkin, Jr.	Director	March 12, 2004
/s/ WILLIAM R. ROHN William R. Rohn	Director	March 12, 2004

INDEX TO EXHIBITS

Exhibit Number	Description of Exhibit
23.1	Consent of Ernst & Young LLP, Independent Auditors.
31.1	Certification of the Chief Executive Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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Exhibit 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements (Form S-8) pertaining to the 1996 Equity Incentive Plan, Employee Stock Purchase Plan, 1998 Non-Officer Stock Option Plan and 1999 Equity Incentive Plan, and Registration Statements on Form S-3 (Nos. 333-93481, 333-47224, 333-61460, 333-61910 and 333-67286), of Cerus Corporation of our report dated January 23, 2004 with respect to the financial statements of Cerus Corporation included in its Annual Report (Form 10-K) for the year ended December 31, 2003, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Palo Alto, California
March 10, 2004

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Exhibit 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

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Exhibit 31.1

CERTIFICATION

I, Stephen T. Isaacs, certify that:

1. I have reviewed this annual report on Form 10-K of Cerus Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) [intentionally omitted]

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2004

/s/ STEPHEN T. ISAACS

Stephen T. Isaacs
Chief Executive Officer

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Exhibit 31.1

CERTIFICATION

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Exhibit 31.2

CERTIFICATION

I, Gregory W. Schafer, certify that:

1. I have reviewed this annual report on Form 10-K of Cerus Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) [intentionally omitted]

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2004

/s/ GREGORY W. SCHAFER

Gregory W. Schafer
Chief Financial Officer

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Exhibit 31.2

CERTIFICATION

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Exhibit 32.1

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Stephen T. Isaacs, the Chief Executive Officer of Cerus Corporation (the "Company"), and Gregory W. Schafer, the Chief Financial Officer of the Company, hereby certify that, to the best of their knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2003, and to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of section 13(a) or section 15(d) of the Securities Exchange Act of 1934, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF **,** the undersigned have set their hands hereto as of the 12th day of March, 2004.

/s/ STEPHEN T. ISAACS	/s/ GREGORY W. SCHAFER
Chief Executive Officer	Chief Financial Officer

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Exhibit 32.1

CERTIFICATION