CERUS CORP

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, 2005
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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 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. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

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 $69,789,418.(1)

As of February 17, 2006, there were 22,509,555 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 2006 annual meeting of stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than April 30, 2006, are incorporated by reference into Part III of this annual report on Form 10-K.

(1) Based on a closing sale price of $4.43 per share on June 30, 2005. Excludes 6,585,725 shares of the registrant's common stock held by executive officers, directors and affiliates at June 30, 2005.

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PART I

This report contains forward-looking statements that involve risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "expect," "plan" and similar expressions are intended to identify such forward-looking statements. There can be no assurance that these statements will prove to be correct. Certain important factors could cause actual results to differ materially from those discussed in such statements, including whether our preclinical and clinical data will be considered sufficient by regulatory authorities to grant marketing approval, market acceptance of our products, development and testing of additional configurations of our products, regulation by domestic and foreign regulatory authorities, a transition away from a reliance on Baxter for sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Baxter and third parties to manufacture certain components of the INTERCEPT Blood System, our successful completion of our product components' commercial design, our reliance on our relationship with BioOne Corporation, the early stage of development of our vaccine programs, our ability to attract and retain partners and collaborators for our immunotherapy programs, more effective product offerings by , or clinical setbacks of , our competitors, product liability, our use of hazardous materials in the development of our products, business interruption due to earthquake, our limited operating history and expectation of continuing losses, the need for additional financing, protection of our intellectual property rights, volatility in our stock price, legal proceedings, on-going compliance with the requirements of the Sarbanes-Oxley Act of 2002 and other factors discussed below and under the caption "Risk Factors," and in our other documents filed with the Securities and Exchange Commission. We undertake no obligation to update any of the forward-looking statements contained herein to reflect any future events or developments.

Cerus , *Helinx*, *INTERCEPT* and *INTERCEPT Blood System* are United States registered trademarks of Cerus Corporation. *Baxter* is a trademark of Baxter International Inc.

Item 1. *Business*

Overview

We are developing and commercializing novel, proprietary products and technologies within the fields of immunotherapy and blood safety that are intended to provide safer, more effective medical options to patients in areas of substantial unmet medical need. In the field of immunotherapy, we are employing our proprietary attenuated *Listeria* vaccine platform to develop a series of novel therapies to treat cancer. We currently have three immunotherapeutic cancer vaccine product candidates, one of which is anticipated to enter clinical trials in the first half of 2006 and two of which are in preclinical development. These product candidates are designed to stimulate both innate and adaptive immune pathways, generating highly specific and highly potent anti-tumor responses. We are collaborating in the development of these product candidates with investigators at The Johns Hopkins University, or Johns Hopkins, and with MedImmune, Inc., or MedImmune. Also in immunotherapy, we are applying our proprietary Killed But Metabolically Active, or KBMA, technology platform in research and development of prophylactic and therapeutic vaccines for infectious diseases, including hepatitis C. We have two prophylactic KBMA vaccine product candidates in early stages of development, one against anthrax and the other against tularemia. Both of these programs have received funding from the National Institutes of Health, or NIH, under national bioterrorism initiatives. In the field of blood safety, we are developing and commercializing the INTERCEPT Blood System for platelets, plasma and red blood cells, or INTERCEPT Blood System. The INTERCEPT Blood System, which is based on our proprietary Helinx technology for controlling biological replication, is designed to enhance the safety of donated blood components by inactivating viruses, bacteria, parasites and other pathogens, as well as potentially harmful white blood cells.

We have worldwide commercialization rights for the INTERCEPT Blood System for platelets, plasma and red blood cells, excluding certain countries in Asia where we have licensed commercialization rights to the platelets and plasma systems to BioOne Corporation, or BioOne. We previously collaborated with subsidiaries of Baxter International Inc., or Baxter, in the development and commercialization of the INTERCEPT Blood

System. In February 2005 and February 2006, we announced agreements with Baxter that resulted in our acquisition of all commercialization rights to the INTERCEPT Blood System that have not been licensed to BioOne. The INTERCEPT Blood System for platelets has received CE mark approval in Europe and is being marketed for commercial sale in those countries that do not require an additional national review and approval. With Baxter, we submitted an application in late 2005 for CE mark approval in Europe for the INTERCEPT Blood System for plasma. We have prioritized the commercialization of the INTERCEPT Blood System for platelets and plasma in Europe ahead of our regulatory approval activities in the United States relating to these systems, but we continue to be in communication with the United States Food and Drug Administration, or FDA, regarding the regulatory pathway for the INTERCEPT Blood System in the United States.

We were incorporated in California in 1991 and reincorporated in Delaware in 1996. Information regarding our revenue, net income or losses, and total assets for the last three fiscal years can be found in the financial statements and related notes found elsewhere in this report.

Product Development

We have incurred total research and development expenses of $24.1 million, $27.7 million and $52.5 million for the years ended December 31, 2005, 2004 and 2003, respectively. The following table identifies our products and product development programs and their current status:

Product or Product Under Development	Potential Therapeutic Indication/Use	Development Status	Commercial Rights
Immunotherapy – Attenuated Listeria Platform			
CRS-100 (attenuated Listeria)	Cancers that have metastasized to the liver, including colorectal cancer	Preclinical development complete; initiation of Phase I clinical trial anticipated in first half of 2006	Cerus
CRS-207 (attenuated *Listeria* expressing Mesothelin antigen)	Pancreatic and ovarian cancer	Preclinical development	Cerus
MEDI-543 (EphA2) (attenuated *Listeria* expressing EphA2 antigen)	Breast, prostate and colon cancers and metastatic melanoma	Preclinical development	MedImmune
Immunotherapy – KBMA Platform			
Anthrax Vaccine	Prophylactic vaccine against anthrax	Preclinical research and development	Cerus
Tularemia Vaccine	Prophylactic vaccine against tularemia	Preclinical research and development	Cerus
Blood Safety			
INTERCEPT Blood System—Platelets	Inactivation of viruses, bacteria and other pathogens in platelets for transfusion	Europe: Commercialized in certain countries U.S.: Phase III clinical trial completed; supplemental clinical trial likely to be required	Cerus worldwide except rights granted to BioOne in certain Asian countries
INTERCEPT Blood System – Plasma	Inactivation of viruses, bacteria and other pathogens in plasma for transfusion	Europe: CE mark application submitted late 2005 U.S.: Phase III clinical trials completed	Cerus worldwide except rights granted to BioOne in certain Asian countries
INTERCEPT Blood System – Red Blood Cells	Inactivation of viruses, bacteria and other pathogens in red blood cells for transfusion	Research and development based on prior Phase III data ongoing; re-entry into Phase I trial anticipated in mid 2006	Cerus

Immunotherapy

Background

We are using our proprietary, versatile vaccine platforms to develop therapies to stimulate the immune system to selectively target and attack cancer cells and infectious diseases. This vaccine platform is based on specially designed and proprietary strains of the bacterium *Listeria monocytogenes* . We believe that our proprietary strains of *Listeria*, alone or expressing cancer antigens, have the potential to harness the power of the immune system to selectively attack cancer cells. In September 2004, preclinical efficacy and safety data for our attenuated *Listeria* -based cancer immunotherapy technology were published in the *Proceedings of the National Academy of Sciences* , or PNAS. The PNAS paper described studies in which experimental vaccines based on our proprietary *Listeria* platform were engineered to express specific tumor antigens. These vaccines were shown to elicit therapeutic anti-tumor responses in tumor-bearing mice, resulting in prolonged survival. In addition, the *Listeria* strain used in these studies demonstrated a one thousand-fold reduction in toxicity when compared to wild-type *Listeria* .

In comparison to other strains, the optimized platform *Listeria* strain used in the studies was cleared more rapidly *in vivo* and showed significantly higher safety margins while preserving immunogenic potency. When used at comparable doses to unmodified *Listeria* , the optimized strain generated equivalent immune responses, yet could be administered at higher doses, resulting in more potent T cell responses than possible with wild-type *Listeria* . Finally, therapeutic administration of an experimental vaccine using the optimized strain resulted in a significant reduction in metastases and a significant increase in survival in mice with established tumors.

In addition to our attenuated *Listeria* vaccine platform, we have developed a second immunotherapy platform based on our KBMA technology. We currently are utilizing this platform to develop therapeutic and prophylactic vaccines for serious infectious diseases. Our KBMA platform is based on the application of our proprietary Helinx technology, which is designed to bind with the DNA of infectious pathogens resulting in their inability to replicate. Using this method, we are able to inhibit the infectivity, but maintain the metabolic activity of specially engineered, proprietary pathogens. Accordingly, we are seeking to develop KBMA vaccine candidates that retain the potency typically found in live viral and bacterial vaccines, but with the safety advantages of killed vaccines. A scientific paper detailing preclinical data on KBMA *Listeria* as a vaccine platform appeared in the August 2005 edition of *Nature Medicine* . Early research and development efforts relating to our KBMA technology platform have been funded in part by grants from the NIH and the National Institute of Allergy and Infectious Diseases, or NIAID, both of whom are interested in this technology for biodefense applications.

Product Candidates and Development Activities

Our Attenuated Listeria Vaccine Platform

CRS-100

We have conducted preclinical development of a strain of proprietary attenuated *Listeria* for use in treating liver metastases of certain cancers, including colorectal cancer. Preclinical experiments of our product candidate, CRS-100, suggest that our *Listeria* strain selectively stimulates an anti-cancer immune response in the liver. When administered intravenously to mice, CRS-100 is taken up by macrophages in the liver and induces a cascade of immune stimulating cytokines and chemokines. This inflammatory response leads to the recruitment and activation of immune cells to the liver, such as Natural Killer cells that mediate anti-tumor effects, and dendritic cells that prime long-lasting immunity against the tumor. We have conducted toxicology studies of CRS-100 in non-human primates and filed an investigational new drug application, or IND, with the FDA in late 2005. We expect to initiate a Phase I clinical trial of CRS-100 in the United States in the first half of 2006, subject to approval by institutional review boards at our investigational sites, among other factors.

CRS-207

In collaboration with investigators at Johns Hopkins, we are conducting preclinical studies of a therapeutic pancreatic cancer vaccine candidate, CRS-207, using the same proprietary strain of attenuated *Listeria* used in CRS-100, but in this product application the strain is engineered to express Mesothelin. Mesothelin is an antigen that is prevalently expressed in pancreatic and ovarian tumors, but not in normal pancreatic or ovarian tissue. In clinical studies at Johns Hopkins, three pancreatic cancer patients vaccinated with an experimental, non- *Listeria* vaccine developed T cell responses against Mesothelin, and those patients are alive and disease free more than seven years after their initial cancer diagnosis. Cytotoxic T cells isolated from these patients recognized and destroyed tumor cells *in vitro* , further validating Mesothelin as a target in pancreatic cancers. In December 2003, we licensed certain rights to Mesothelin from Johns Hopkins. In December 2004, we entered into an exclusive license with Chugai Pharmaceutical Co., Ltd., relating to the DNA sequence of Mesothelin in the field of cancer vaccines.

MEDI-543 (EphA2)

In April 2004, we entered into an agreement with MedImmune to co-develop a novel immunotherapeutic vaccine for cancer. This product candidate, MEDI-543 (EphA2), combines our attenuated *Listeria* platform with MedImmune's proprietary EphA2 antigen, which is expressed in a number of solid tumor cancers. According to a paper published on August 1, 2004 in *Clinical Cancer Research* by researchers from the University of Texas M.D. Anderson Cancer Center, elevated levels of EphA2 have been linked to cancer progression and decreased patient survival in ovarian cancer patients. EphA2 is also known to be overexpressed by other types of cancers, including breast, prostate and metastatic melanoma.

Under the terms of the agreement, we have conducted preclinical development activities in support of MedImmune who is responsible for preclinical development, clinical testing, manufacturing and commercialization of any product resulting from the collaboration. We have received development funding from MedImmune and may receive contingent milestone payments and royalties on future product sales. In September 2005, MedImmune selected a lead candidate strain as a predicate to advanced preclinical testing.

KBMA Platform

Anthrax Vaccine

In July 2004, we were awarded a $3.8 million grant from the NIH to begin development of a prophylactic anthrax vaccine based on our KBMA vaccine platform. This award is shared with a consortium of researchers at the University of California at Berkeley and the University of New Mexico Health Sciences Center, with Cerus serving as the principal investigator. Exposure to the bacterium *Bacillus anthracis* leads to a serious and life-threatening infectious disease and has become a major concern due to its potential to be used as an agent for bioterrorism. The only currently licensed human anthrax vaccine was developed in the late 1950's and has limited efficacy. We believe that an anthrax vaccine based on our KBMA platform technology has the potential to offer greater potency than the current vaccine. To date, we have demonstrated that a KBMA anthrax vaccine has the ability to induce broad-based immune responses and protect mice from developing anthrax after exposure to a usually lethal dose of anthrax spores.

Tularemia Vaccine

In October 2005, we announced that a consortium of which we are a member was awarded $24.8 million from the NIAID for the study of the basic biology of and development of a prophylactic vaccine against *Francisella tularensis* , the bacterium that causes the infectious disease tularemia. Of the total award amount, we expect to receive $2.8 million over a three-year period. Tularemia, also known as Rabbit Fever, is a serious and life-threatening infectious disease for which there is currently no effective human vaccine. Similar to anthrax, tularemia has emerged as a growing bioterrorism concern because of its high level of infectivity, ease of

dissemination and substantial mortality rate. Our work with the consortium will center on the development of a prophylactic tularemia vaccine using our KBMA technology platform, and we and our collaborators are currently constructing vaccine candidates.

Hepatitis B and C Vaccines

We believe that our KBMA technology has the potential to be used to develop novel therapeutic vaccines for serious infectious diseases, such as hepatitis B and C. Both hepatitis B and C establish chronic infections in the liver, and both can be treated with a combination of small molecule drugs and interferon, an immune-activating protein. However, current treatments are suboptimal because systemic interferon treatment is difficult for patients to tolerate and induces a flu-like syndrome. Our approach is to utilize our KBMA platform to produce killed but metabolically active strains of *Listeria* . We believe that these strains would take advantage of *Listeria's* natural tropism, or biological affinity, to the liver and induce localized production of cytokines, notably including interferon, that, in combination with small molecule drugs, may lead to elimination of hepatitis viruses. We believe that our KBMA platform will also allow us to engineer KBMA *Listeria* strains that express hepatitis antigens, in order to elicit a specific and long-lasting T cell response against virally infected tissues. Our expectation is that this approach may be better tolerated and have a higher rate of efficacy than current immunotherapies. We intend to leverage the experience and know-how from our research and development efforts in prophylactic vaccines against anthrax and tularemia to develop therapeutic vaccines for other infectious diseases.

Blood Safety

Background

The INTERCEPT Blood System is designed to broadly target and inactivate blood-borne pathogens, such as viruses (HIV and hepatitis B and C, for example), bacteria and parasites, as well as potentially harmful white blood cells, while preserving the therapeutic properties of platelet, plasma and red blood cell transfusion products. The INTERCEPT Blood System inactivates a broad array of pathogens and has the potential to reduce the risk of transfusion related 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 most new pathogens before they are identified and before tests are developed and adopted to detect their presence in donated blood. The INTERCEPT Blood System is based on our proprietary Helinx technology for controlling biological replication.

We have worldwide commercialization rights for the INTERCEPT Blood System, excluding certain countries in Asia. We previously collaborated with Baxter and currently are collaborating with BioOne on the commercialization of the INTERCEPT Blood System in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore.

Products, Product Candidates and Development Activities

INTERCEPT Blood System for Platelets

The INTERCEPT Blood System for platelets, or platelet system, is designed to inactivate blood-borne pathogens in donated platelets for transfusion. The platelet system has received CE mark approval in Europe and is being marketed and sold in several countries in Europe. However, we will need to complete validation studies and obtain regulatory and/or reimbursement approvals in some individual European countries to market the platelet system in those countries, which include England, France and Germany. The extent of the validation studies varies by country. Further clinical studies, ranging from small-scale experience studies to larger randomized trials, will be conducted in some regions and countries, such as the Netherlands, Germany and France. These studies may be conducted to gain broader market acceptance, expand product labeling or provide data to support applications for regulatory and/or reimbursement approval. Furthermore, in certain countries,

including England and Germany, the platelet system must be approved for purchase or use by a specific governmental or non-governmental entity or entities, such as the Paul Ehrlich Institute in Germany, after which reimbursement rates will need to be determined. In France , the platelet system has been approved for use by blood centers in treating platelets, but we do not expect widespread commercial adoption of the platelet system to occur until we have successfully completed certain experience studies and national reimbursement levels have been determined.

We completed a Phase III clinical trial of the platelet system 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, an independent expert physician panel performed an additional analysis of some of the clinical trial data, which was collected by an independent contract research organization, to determine if a small number of apparent differences between treatment groups in the category of pulmonary adverse events reported in the study were attributable to inconsistent event reporting. The assessments of primary patient records on a blinded basis by the independent expert physician panel found no statistically significant differences in clinically significant pulmonary adverse events between test and control groups. These assessments differed from adverse events drawn from the case report forms from the Phase III clinical trial, which showed statistically significant differences in specific pulmonary events. Furthermore, this assessment supported our interpretation that the imbalance observed based on the case report forms was due to reporting differences among the clinical sites. Together with Baxter, we submitted in 2005 a final report of the analysis to the FDA for review. The final report included conclusions from the expert physician panel. Prior to receiving this document, the FDA had requested that a supplemental Phase III clinical trial be conducted, and we continue to expect that the FDA will require a randomized, blinded clinical trial before a product license application can be finalized and the platelet system considered for approval in the United States.

INTERCEPT Blood System for Plasma

The INTERCEPT Blood System for plasma, or plasma system, is designed to inactivate blood-borne pathogens in donated plasma for transfusion. We completed the last of three planned Phase III clinical trials of the plasma system in 2004, and the primary and secondary efficacy endpoints of the trial for therapeutic plasma exchange were met. The study showed no clinically and statistically significant differences in overall adverse events between the treatment group and the control group. Based on the results of the Phase III clinical trials, we filed a CE mark application for the plasma system in December 2005 and have prioritized attaining CE mark approval and subsequent commercial launch of the plasma system in Europe ahead of further regulatory efforts relating to the plasma system in the United States. A final Phase III report was submitted to the FDA in 2005.

INTERCEPT Blood System for Red Blood Cells

The INTERCEPT Blood System for red blood cells, or red blood cell system, is designed to inactivate blood-borne pathogens in donated red blood cells for transfusion. In September 2003, we terminated Phase III clinical trials of the red blood cell system due to the detection of antibodies in two patients. We evaluated the antibodies detected in the trial and developed process changes that may greatly diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. We announced several findings related to these evaluations and developments in late 2004 and 2005 at several scientific and trade association meetings. Based on these findings and other preclinical work we have conducted, we intend to re-enter Phase I clinical trials for the red blood cell system in the United States in mid 2006 with our modified process, subject to requisite study site approvals, among other factors.

Collaborations

MedImmune

In April 2004, we entered into an agreement with MedImmune to co-develop a novel therapeutic vaccine designed to target antigens expressed in breast, prostate and colon cancer, as well as metastatic melanoma. We

are developing MEDI-543 (EphA2) using our *Listeria* vaccine platform and MedImmune's EphA2 cancer antigen. Under the terms of the agreement, we have conducted preclinical development activities in support of MedImmune who is responsible for preclinical development, clinical testing, manufacturing and commercialization of any product resulting from the collaboration, and development of a therapeutic vaccine candidate. We are receiving development funding and may receive contingent milestone payments and royalties on future product sales. As of December 31, 2005, we had received up front and milestone payments of $1.5 million from MedImmune under the terms of the agreement, consisting of a $1.0 million up front payment and a $0.5 million milestone payment. We also recognized $2.4 million and $1.6 million of development funding during the years ended December 31, 2005 and 2004, respectively.

Baxter

We have been collaborating with Baxter on the development and commercialization of the INTERCEPT Blood System since 1993. Effective February 1, 2006, we entered into a restructuring of our agreements with Baxter pursuant to which we obtained exclusive worldwide commercialization rights to market, distribute and sell the platelet and plasma systems, excluding certain Asian countries where we have licensed rights to BioOne. We regained worldwide commercialization rights to market the red blood cell system from Baxter in February 2005. In connection with the transfer of commercialization rights to us, Baxter has agreed to supply, at our expense, certain transition services, including regulatory, technical and related administrative support until December 31, 2006. We have agreed to purchase UVA illumination devices from Baxter and may purchase other finished goods and work in process from Baxter's inventory for use with the platelet and plasma systems. Baxter has agreed to manufacture systems and components for the platelet and plasma systems on a cost-plus basis through December 31, 2008 and has agreed to supply only very limited types of components for the prototype of the red blood cell system. We will be obligated to pay Baxter royalties on future INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system, 3% for the plasma system and 5% for the red blood cell system. As a result of the agreement, we expect to recognize gains of $6.5 million in 2006.

BioOne

In June 2004, we entered into an agreement with Baxter and BioOne for commercialization of our platelet system in specified parts of Asia. Under the terms of the agreement, BioOne is responsible, at its expense, for seeking regulatory approvals for the platelet system in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore in exchange for exclusive marketing and distribution rights in each of those countries. We have received a total of $10 million in up-front payments under the terms of the agreement and will be eligible to receive contingent milestone payments for our sole account and royalties on future product sales, which will be shared equally by Baxter and us.

In June 2005, we announced our entry into a definitive agreement with Baxter and BioOne for commercialization of our plasma system in specified parts of Asia. Under the terms of the definitive agreement, BioOne is responsible, at its expense, for seeking regulatory approvals for the plasma system in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore in exchange for exclusive marketing and distribution rights in each of those countries. We have received a total of $5.0 million in cash and $5.0 million in BioOne equity securities in connection with the definitive agreement and will be eligible to receive (i) contingent milestone payments, payable to us solely; and (ii) royalties on future product sales, which will be shared by Baxter and us.

U.S. Armed Forces

In February 2001, we were awarded $2.6 million under a cooperative agreement with the Army Medical Research Acquisition Activity division of the Department of Defense. In September 2002, May 2003, January 2004 and July 2004, we were awarded additional funding of $5.0 million, $6.0 million, $5.5 million and $3.7

million, respectively, all of which was for the continued funding of projects to develop our pathogen inactivation technologies to improve the safety and availability of blood for medical transfusions. Under the terms of the agreements, we are conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites, which are of concern to the U.S. armed forces.

Manufacturing and Supply

We have used, and intend to continue to use, third parties to manufacture and supply the immunotherapy product candidates and inactivation compounds for the INTERCEPT Blood System for use in clinical trials and for commercialization. We have no experience in manufacturing products for commercial purposes and have only limited manufacturing facilities capable of producing small lots of preclinical materials for our immunotherapy programs. Consequently, we are dependent on contract manufacturers for the production of immunotherapy materials and Helinx compounds and on Baxter for other INTERCEPT Blood 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 for the platelet and plasma systems, such as blood storage containers and related tubing, as well as any device associated with the inactivation process on a cost-plus basis through 2008.

We have contracted with one manufacturing facility for the synthesis of amotosalen, an inactivation compound used in our platelet and plasma systems. Under this contract, we are not subject to minimum annual purchase requirements. However, if specified quantities of amotosalen are not purchased in any year, 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 platelet and plasma systems, and to support near-term sales of the platelet system in Europe.

We and our contract manufacturers 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 the INTERCEPT Blood System is dominated by a small number of blood collection organizations in the United States, Western Europe and Japan, where various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood component supplies. The largest European markets for our products are in England, Germany and France. Decisions on product adoption are centralized in England. 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 England. Reimbursement rates for platelet pathogen inactivation must be set before we would expect broad commercial adoption of the platelet system in France. In addition, our 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.

For logistical and financial reasons, the transfusion industry has not always integrated new technologies into their processes, even those technologies with the potential to improve the safety of the blood supply. In addition, healthcare professionals may require further safety information or additional studies before adopting our

products. 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, blood centers, physicians, patients and healthcare payors may not believe that the benefits of using our products justify their additional cost. Furthermore, our products may be inappropriate for certain patients, which could reduce the potential market size.

There is some volume loss in the yield of blood products as a result of our pathogen inactivation process. In addition, our process today is not fully compatible with the common practice of collecting two units of platelets from a single apheresis donor. If the volumetric reduction of blood product leads to increased costs, or our process requires changes in blood center or 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.

Prior to February 2006, Baxter had been responsible for the marketing, sales and distribution of the platelet system in the United States, Europe and other regions not covered by the agreements with BioOne. Baxter also had been responsible for the marketing, sales and distribution of the plasma system following marketing approval in Europe and other countries, excluding North America, and the regions covered by the agreements with BioOne. We currently have a small scientific affairs group that has helped support the commercialization efforts of Baxter and BioOne. As a consequence of the February 2006 agreement with Baxter, we are developing our own independent marketing and sales organization to market and sell the INTERCEPT Blood System in Europe, while continuing to rely upon BioOne's organization in Asia.

Under our April 2004 agreement, MedImmune is responsible for sales and marketing of any products resulting from our collaboration. We are solely responsible for the continued development, clinical trials, regulatory approval and subsequent marketing and sales of our immunotherapy product candidates that are not partnered. It will take a long time for us to complete preclinical development, clinical trials and regulatory approval for one or more of our immunotherapy product candidates. Before we submit any applications for regulatory approval of these products, we expect to have a sales and marketing plan in place, which could include formation of internal sales and marketing functions, collaborating with one or more third-parties with sales and marketing capabilities, or both.

Competition

We believe our approaches to cancer and infectious disease immunotherapy have certain competitive advantages over currently available treatments or those now in development. However, the markets for treatments of cancer and infectious disease are intensely competitive and subject to rapid change. Many companies with significantly greater resources than ours have established products on the market, as well as promising product candidates in more advanced development stages than our programs. Our ability to bring to market products that achieve a significant degree of commercial success will be dependent on a number of factors, including their relative efficacy and safety as shown in human clinical trials, our ability to receive regulatory approval to sell products in the United States and in foreign jurisdictions, our ability to scale up and manufacture at acceptable cost, the availability of reimbursement from managed care organizations, and our ability to establish distribution channels for our products.

We believe that the INTERCEPT Blood System has certain competitive advantages over competing blood-borne pathogen inactivation methods that are either on the market, or in development. The INTERCEPT Blood System is designed for use in blood centers on a distributed basis with single units of blood products, which allows for integration 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. In addition, some potential competitors utilize a pooling process prior to pathogen inactivation, which significantly increases the risk of cross-contamination by pathogens that are not inactivated. One competitor has initiated a Phase III clinical trial in France using a pathogen

inactivation process for platelets. Another competitor has developed and is marketing a blood-borne pathogen inactivation product for plasma in Europe. There are no known competitors in the development stage for blood-borne pathogen inactivation of red blood cells. In addition to direct competition from other pathogen inactivation methods, we expect to encounter indirect competition from other approaches to blood safety, including methods of testing blood products for bacterial and viral pathogens.

We believe 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 value, 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 are also important competitive factors. We believe that the INTERCEPT Blood System will compete favorably with respect to these factors, although there can be no assurance that it will be able 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, 2005, we owned approximately 40 issued or allowed United States patents and approximately 50 issued or allowed foreign patents. Our patents expire at various dates between 2009 and 2018. In addition, we have pending United States patent applications and have filed corresponding patent applications under the Patent Cooperation Treaty. We are a licensee under a number of license agreements with respect to United States patents covering inventions pertaining to psoralen-based photochemical decontamination treatment of whole blood or blood components and United States patents relating to our immunotherapy programs, 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

We and our products are comprehensively regulated in the United States by the FDA and, in some instances, by state and local governments, and by comparable governmental authorities in other countries. The FDA regulates drugs, medical devices and biologics under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. These laws and implementing regulations govern, among other things, the development, testing, manufacturing, record keeping, storage, labeling, advertising, promotion and pre-market clearance or approval of products subject to regulation. The steps required before a medical device or biologic may be approved for marketing in the United States pursuant to a pre-market approval application, or PMA, or a biologics license application, or BLA, respectively, generally include (i) preclinical 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 or BLA, as appropriate, and (vi) FDA review of the PMA 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 Practice 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, and a BLA for vaccines for cancer and infectious diseases. In addition, the FDA will require site-specific licenses from our United States-based blood center customers before they can engage in interstate transport of blood components processed using our pathogen inactivation systems, and a delay in obtaining these licenses would adversely impact our ability to sell products in the United States.

Cancer immunotherapies and vaccines for infectious diseases are regulated by the FDA Center for Biologics Evaluation and Research, or CBER. Cerus has filed one investigational new drug application, or IND, and is planning to file one or more applications for immunotherapies in the future. Toxicology studies will be required. Completion of such studies could result in findings that limit the feasibility of one or more particular immunotherapy development programs. There is no assurance at this time that FDA will accept the design of the planned clinical protocols until pre-IND meetings are held. For some immunotherapies, submission to the Recombinant DNA Advisory Committee, or RAC, of the National Institutes of Health will be necessary. The RAC may make recommendations that delay initiation of clinical trials. A series of clinical studies will be necessary to gain sufficient information to submit a BLA to the FDA. Failure of pivotal clinical trials to demonstrate safety and efficacy will preclude moving forward in clinical development or filing of the associated BLA for a product candidate. During the review process for the BLA, it is expected that FDA will request review by an advisory committee, which will make recommendations for or against approval. There are a number of companies pursuing development of cancer immunotherapies. Failure of these types of approaches to demonstrate sufficient efficacy or safety to gain regulatory approval could influence the regulatory process for our product candidates.

The FDA regulates the INTERCEPT Blood System as a biological medical device. CBER 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 blood safety 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. 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 approve a pre-market approval application for the product.

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 the plasma system and red blood cell system to be sold in the European Union. Several European countries require additional in-country studies to support an approval to market the products in such countries.

Baxter has used a modular process for our PMA application for the platelet system in the United States. 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 the INTERCEPT Blood System, there are regulatory requirements applicable to our prospective customers, the blood centers that process and distribute blood and blood products. Blood centers and others will likely be required to obtain approved license supplements from the FDA before using 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 applications 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.

Many of the INTERCEPT Blood System preclinical and clinical studies have been 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 platelet system 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 platelet system 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 our 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 pharmaceuticals, medical devices 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 December 31, 2005, we had 97 employees, 67 of whom were engaged in research and development and 30 in general and administrative activities. 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 Securities Exchange Act of 1934, as amended, or Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. ***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. There may be additional risks faced by our business.

Our vaccine programs are in an early stage of development.

Our vaccine programs are in an early stage of development and there is a high risk of failure. We will be required to perform extensive preclinical and clinical testing before any product candidate can be submitted for regulatory approval prior to commercialization. Clinical testing is very expensive, takes many years, and the outcome is uncertain. Failure to demonstrate the safety or efficacy of a product candidate in preclinical studies or clinical trials would delay or prevent regulatory approval of that product candidate. Our potential vaccine products must meet rigorous testing standards in order to advance to clinical testing. No product candidates employing either our *Listeria* or our KBMA platform technologies have been tested in humans, and preclinical data in animal studies and from *in vitro* experiments may not be predictive of clinical safety and efficacy once product candidates are tested in humans. Our immunotherapy product candidates are unlikely to be used as single agents for the treatment of cancer or infectious diseases, but rather in combination with other drugs and treatment regimens. Testing our vaccines in combination with other drugs and treatment regimens in clinical trials will introduce additional clinical, timeline and regulatory risks and complexities, including added expense, delay in conducting clinical trials and uncertain regulatory requirements.

Naturally-occurring *Listeria* is a bacterium that is a human pathogen that can cause serious illness. Our immunotherapy product candidates for cancer indications use proprietary, modified strains of *Listeria* that are designed to have a substantially reduced ability to cause illness in humans. However, before our vaccine candidates can be accepted for clinical testing, we must successfully complete a number of preclinical safety studies. We may not be able to identify a dose range in which our product candidates are therapeutically effective and yet maintain adequate safety margins. We have filed an IND for our first vaccine candidate, CRS-100, and have obtained clearance from FDA to proceed with a Phase I, dose-escalation clinical trial. We have not yet received approval by any institutional review board (IRB) at a participating clinical site. Clearance of a Phase I clinical trial using CRS-100 does not imply concurrence by FDA to our conducting later stage studies with CRS-100 and does not imply clearance for clinical trials of our other *Listeria* vaccine candidates expressing antigens, such as CRS-207. Our Phase I clinical trial for CRS-100 involves testing in a patient population with advanced disease. We may be unable to test CRS-100 and our other product candidates in subsequent trials in patient populations that we believe may be better suited clinically or commercially to our vaccines.

Because our vaccine candidates use novel platforms, the FDA or foreign regulators may require studies that we have not anticipated. In addition, we have contracted with third-party manufacturers to produce our vaccines

for research, preclinical and clinical testing. We have manufactured CRS-100 for toxicology studies and Phase I clinical trials, but have not engaged in scale-up of the manufacturing process or the development of a commercial formulation. We rely on third parties to conduct aspects of preclinical development on our behalf, including contract manufacturing and research services. These third parties may encounter delays, over which we have significantly less control than research and development activities performed in-house, or experience unexpected results. We may experience numerous unforeseen events during, or as a result of, the preclinical research and development process that could delay or prevent clinical testing, regulatory approval and commercialization of our potential products.

Our ability to successfully develop cancer and infectious disease products is dependent in part on being able to attract and retain partners and collaborators, as well as governmental funding sources.

The development and commercialization of product candidates employing our Listeria and KBMA platform technologies will be expensive, lengthy and uncertain. To date, we have relied not only upon internal scientific, development and financial resources, but also upon third parties. We have licensed our Listeria platform to MedImmune for use in developing a product candidate for certain cancers. We are collaborating with investigators at Johns Hopkins on other cancer and infectious disease programs. We also rely on advice and insights from our scientific advisory board, a group of independent clinicians, professors and investigators, regarding our research and development activities. These relationships provide us with external perspectives and independent validation that may be critical to our future success. Loss of these relationships or failure to attract others may result in additional expense, delays in development and regulatory approval and failure to commercialize products. We have received significant funding from U.S. government agencies for research and development in both cancer and infectious disease, as well as funding from MedImmune under our license agreement relating to development of MEDI-543 (EphA2). Due to budgetary constraints, funding from the Federal government, particularly funding from the Department of Defense and National Institutes of Health, is expected to be reduced from prior years and is subject to political and economic forces beyond our control. Federal funding in support of our programs to develop prophylactic vaccines against anthrax and tularemia is not expected to lead to substantial commercial opportunities beyond potential biodefense applications, and we cannot be certain that the research conducted into those two infectious diseases will readily translate into applications with greater commercial potential. Loss of funding from government sources and third parties would require us to reduce the scope of our research and development efforts in immunotherapeutics, narrowing the number of programs to those we could support through internal resources.

If our preclinical and clinical data are not considered sufficient by regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue.

Except for the INTERCEPT Blood System for platelets, or platelet system, 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 product candidates must satisfy rigorous standards of safety and efficacy before the FDA and international regulatory authorities can approve them for commercial use. We must provide the FDA and international regulatory authorities with preclinical, 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 platelet system received CE mark approval in Europe. We will need to complete validation studies and obtain regulatory and reimbursement approvals in certain European countries before we can market our products in those countries. Further randomized clinical trials funded by third parties will be conducted in some European countries, such as the Netherlands. We expect to conduct many smaller scale experience trials with prospective customers in a number of European countries. We expect that decisions to adopt the platelet system may be deferred until completion of the additional trials and experience studies in Europe and

reimbursement rates are set. In certain countries, including England and Germany, the system must be approved for purchase or use by a specific governmental or non-governmental entity or entities, such as the Paul Ehrlich Institute in Germany, after which reimbursement rates will need to be determined. In France, the platelet system has been approved for use by blood centers in treating platelets; however, we do not expect to sell the platelet system to commercial customers until we have successfully completed certain experience studies and national reimbursement levels have been set.

We completed our Phase III clinical trial of the platelet system 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 performed an additional blinded analysis of the clinical trial data, under the direction of an independent expert physician panel, to determine if apparent differences between treatment groups in the category of pulmonary adverse events reported in the study were attributable to inconsistent event reporting. The reassessment of primary patient records by the expert physician panel showed no statistically significant differences between groups. This reassessment differed from the earlier analysis of adverse events that was based on clinical trial case report forms, which showed statistically significant differences in specific pulmonary events. We submitted a report of the analysis to the FDA for review. The report included conclusions from the expert physician panel. Even if the results of this analysis are satisfactory to the FDA, we expect the FDA to require a supplemental clinical trial to evaluate the hemostatic efficacy and safety of the platelet system, prepared using our final commercial product design, as compared to conventional platelets. The supplemental clinical trial would need to be completed and data from the trial submitted to the FDA before we could complete our regulatory submission. The FDA may not find the results of the expert physician panel analysis 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, Phase IIIb and Phase IIIc clinical trials of the INTERCEPT Blood System for plasma, or plasma system, in the United States, reports for which were filed with the FDA during 2005. Baxter and we submitted a CE mark application for regulatory approval in Europe of the plasma system in December 2005. We have not submitted any applications for regulatory approval of the plasma system in the United States or any other regions other than Europe. In some countries, including those in Europe, we may be required to perform additional clinical studies using the commercial configuration of the system in order to obtain regulatory approval. Failure to pursue regulatory approval of the plasma system in the U.S. due to strategic priorities may have adverse consequences on market acceptance of the INTERCEPT Blood System globally.

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 have been conducting additional research activities on our red blood cell system to determine if the system can be reconfigured to reduce the potential for antibody reactivity to treated red blood cells. Based upon an internal evaluation of the results to date from these additional research activities and after consulting with regulatory authorities, we have elected to initiate new Phase I trials in 2006 in the United States using a modified red blood cell system before potentially progressing to later-stage clinical trials. We will utilize a manual processing system in Phase I trials, which system is not in a commercially feasible form. A number of process and product design issues that could impact efficacy and market acceptance will need to be resolved prior to the initiation of clinical trials and while those clinical trials are being conducted. These include development of a commercially feasible red blood cell system, including disposables, hardware and software for implementing the process in blood collection centers. A delay in completing such activities could result in a delay in initiating Phase I trials or progressing to later stage trials. If we are unsuccessful in advancing a modified red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our development expenses incurred to date in the red blood cell system 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. Enrollment criteria for certain of our clinical trials may be quite narrow. Consequently, we may be unable to recruit suitable patients into the trial on a timely basis, if at all. 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. In addition, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial or adverse medical events during a clinical trial could cause a preclinical 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.

The INTERCEPT Blood System may not achieve broad market acceptance.

Under our previous agreements, Baxter's sales and marketing organization had made only modest progress in commercializing the platelet system in European countries where it has been fully approved for sale. Despite CE mark approval, Baxter had encountered governmental and blood banking community resistance to commercial adoption, including concerns from some national transfusion services, governmental agencies and healthcare policy groups regarding efficacy, cost and risk-benefit profile. Some potential customers have indicated that further safety information or additional studies would be required before adopting our products. There is some volume loss in the yield of blood products as a result of our pathogen inactivation process. In addition, our platelet system process today is not fully compatible with the common practice of collecting two units of platelets from a single apheresis donor. If the volumetric reduction of blood product leads to increased costs, or our process requires changes in blood center or clinical regimens, customers may not adopt our platelet system product. Our products do not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens may limit their acceptance.

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, blood centers, physicians, patients and healthcare payors may not believe that the benefits of using the INTERCEPT Blood System justify their additional cost. If customers experience operational or technical problems with the use of INTERCEPT Blood System products, market acceptance may be reduced. For example, if adverse events arise from incomplete inactivation of pathogens, improper processing or user error, or if testing of INTERCEPT Blood System-treated blood samples fails to reliably confirm pathogen inactivation, whether or not directly attributable to a shortcoming of the INTERCEPT Blood System, customers may refrain from purchasing the products.

Market acceptance of our products may also be affected by the availability of reimbursement from governments, managed care payors, such as insurance companies, or other third parties. We have no experience negotiating reimbursement of medical products. In many cases, due to the structure of the blood products industry, we will have little control over reimbursement discussions, which occur between the blood center and its payors. It is difficult to predict the reimbursement status of newly approved, novel medical device or biopharmaceutical products. In certain foreign markets, governments have issued regulations relating to the pricing and profitability of medical products and medical products companies. There also have been proposals in the United States, at both the federal and state government level, to implement such controls. The widespread adoption 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 we can obtain for our products.

We may be required to reduce the sales price for our products, which would reduce and may eliminate our gross profit on sales. At our present low unit sales levels of the platelet system, our costs to manufacture and sell the platelet system are in excess of revenue. We may be unable to increase sales to a level sufficient to generate profits. We believe that future product sales in Europe and other regions may be negatively affected because we do not have FDA approval for any of our products. If the INTERCEPT Blood System products fail to achieve market acceptance, we may never become profitable.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Even if our products receive regulatory approval and reimbursement is available, failure to properly market, price or sell our products to any of these large customers could significantly diminish potential product revenue in those geographies. The market for our pathogen inactivation systems in the United States is highly concentrated, dominated by a small number of blood collection organizations. 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 nation's blood and blood components supply. In Europe, the largest markets for our products are in England, Germany and France. Decisions on product adoption are centralized in England. 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 England or Germany, nor has reimbursement been established in France. The National Blood Service has not yet indicated an interest in implementing our platelet system due to what we understand to be cost-benefit considerations. The Japanese Red Cross controls a significant majority of blood transfusions in Japan. If approvals are not obtained to market our products in these countries, or if the products are not adopted in these countries, our potential product revenue will be significantly decreased.

We will need to develop and test additional configurations of the INTERCEPT Blood System products to address the entire market.

Our efforts to develop the platelet system for use in the United States 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, though a significant minority is prepared from pooled random donor platelets derived from whole blood collections. Blood centers in the United States preparing pooled random donor platelets may be reluctant to switch to apheresis collection. 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 additional clinical trials. These development activities would increase our costs significantly, and may not be successful. In addition, FDA regulations limit to four hours the time from pooling to transfusion to minimize the proliferation of bacterial contamination in the pooled product. 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 request for the FDA to do so.

Our products, blood products treated with the INTERCEPT Blood System and we are subject to extensive regulation by domestic and foreign authorities.

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

- development;
- testing;
- manufacturing;
- labeling;
- storage;
- pre-market clearance or approval;
- sales and distribution;
- use standards and documentation;

- post-launch surveillance;
- advertising and promotion; and
- 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, and 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 the INTERCEPT Blood System 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. BPAC will make a recommendation to the FDA for, or against, approval. Even if BPAC were to recommend approval of one or more of our products, the FDA would not necessarily approve those products. If BPAC were to recommend against approval of one or more of our products, it is likely that the FDA would not approve those products. Product candidates in our immunotherapy programs beyond CRS-100 will be subject to review by the Recombinant DNA Advisory Committee of the National Institutes of Health, which could delay initiation of clinical trials.

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 Practice. The failure to comply with these requirements could result in delaying or precluding commercialization efforts in certain geographies, including the United States, and could result in enforcement action, which could harm our business. Gaining FDA approval for our platelet and plasma products will require additional investment and time, because the current manufacturing sites we rely upon for producing the platelet and plasma system products for European distribution are not FDA-qualified facilities. Regulatory authorities may also require post-marketing testing, which can involve significant expense. Because of the limited duration and number of patients receiving blood components treated with the INTERCEPT Blood System products in clinical trials, it is possible that harmful effects of our products not observed in clinical and preclinical testing could be discovered in later stage clinical trials or after a marketing approval has been received. 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. Governments or regulatory authorities may impose new regulations or other changes that could further delay or preclude regulatory approval of our potential products. We cannot predict the impact of adverse governmental regulation that might arise from future legislative or administrative action.

Distribution of our products outside the United States also is subject to extensive government regulation. These regulations 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 European Union-level approval, we must obtain regulatory and reimbursement approvals in some individual European countries, including France, Germany and England, to market our products. In addition, our customers in many countries must obtain regulatory approval to sell blood components treated with the INTERCEPT Blood System. 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.

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 or immunotherapies; and
- manufacturing and stability studies.

We have conducted many toxicology studies to demonstrate the INTERCEPT Blood System product candidates' safety, and we plan to conduct toxicology studies for our vaccine candidates and red blood cell system 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 the INTERCEPT Blood System product candidates' 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.

Preclinical testing and clinical trials involving our immunotherapy product candidates are long, expensive and uncertain processes. Neither our *Listeria* nor our KBMA platform technologies have been tested in humans. Consequently, preclinical results in animals and *in vitro* testing may not translate to demonstration of safety and efficacy in human clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advancing stages of clinical trials, even after promising results in earlier preclinical and clinical trials. In addition, regulators and investigators may impose more stringent, time consuming and expensive clinical trial requirements than we might otherwise choose to pursue as a precondition to proceeding with clinical testing. It may take us or our collaborators several years to complete this testing, and failure can occur at any stage of the process.

We do not know whether we or our collaborators will begin planned clinical trials on schedule, if at all. Significant delays in clinical testing could materially impact our clinical trials. We also do not know whether planned clinical trials will need to be revamped or will be completed on schedule, if at all. Criteria for regulatory approval in cancer and infectious disease indications are evolving with competitive advances in the standard of care against which new product candidates are judged, as well as with changing market needs and reimbursement levels. Clinical trial design, including enrollment criteria, endpoints, and anticipated label claims are thus subject to change, even if original objectives are being met. In addition to the reasons stated above, clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, delays in reaching agreement on acceptable clinical study agreement terms with prospective clinical sites, delays in obtaining institutional review board approval to conduct a study at a prospective clinical site and delays in recruiting subjects to participate in a study. We do not know whether any clinical trials will result in marketable products. Typically, there is a high rate of failure for product candidates in preclinical and clinical trials. We do not anticipate that any of our immunotherapy product candidates will reach the market for several years.

Delays can also materially impact our product development costs. If we experience delays in testing or approvals, our product development costs will increase. For example, we may need to repeat clinical trials to address regulatory or clinical questions. We may also need to make additional payments to third-party investigators and organizations to retain their services or we may need to pay recruitment incentives. If the delays are significant, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to become profitable will be delayed.

Regulatory agencies may limit the uses, or indications, for which any of our products are approved. For example, we believe that the INTERCEPT Blood System products 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 of INTERCEPT Blood System products, 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.

We can no longer rely upon Baxter for sales, marketing, distribution and regulatory support of the INTERCEPT Blood System products.

Upon reaching agreements with Baxter in February 2006, we became fully responsible for sales, marketing and distribution support of the INTERCEPT Blood System worldwide, except in those Asian territories covered by our agreements with BioOne for the platelet and plasma systems. As a consequence, we can no longer rely upon Baxter for sales, marketing and distribution support of the INTERCEPT Blood System. Further, the 2006 agreements require that Baxter will provide regulatory support for the INTERCEPT Blood System only through the end of 2006, after which time we can no longer rely on such support from Baxter. We have been particularly dependent on Baxter in Europe, where the platelet system has been approved for sale in certain countries. We will also be dependent on Baxter to transfer know-how relevant to the INTERCEPT Blood System. While the most recent agreements with Baxter call for a transition period in 2006 during which time Baxter will make available, generally at our expense, certain human and organizational resources on an as needed basis, we will need to develop internal competencies in sales, marketing, distribution and regulatory support or arrange for third parties to provide certain of these necessary services in the near future.

- *We have relied on Baxter for marketing, sales, distribution, customer service and back office functions for certain products and regions* . We currently have a small scientific affairs group that has helped support Baxter's marketing organization; however, we have not maintained our own independent sales and marketing organization. We may be unable to maintain existing customer relationships established by Baxter as we take on responsibility for sales, marketing and customer service. Beginning in early 2006, we began to recruit a small sales force dedicated to selling and marketing the platelet system and, if approved, the plasma system, in Europe. We may be unable to recruit suitable sales, marketing, regulatory, quality and back office personnel on a timely basis, if at all. As we reduce our operational reliance on Baxter, we will also need to develop distribution, customer service, and back office capabilities either internally or by contracting with third parties, which we may be unable to accomplish on a timely or affordable basis. Developing sales, marketing and operational capabilities ourselves will increase our costs and may delay commercialization of our pathogen inactivation systems.
- *We have relied on Baxter for regulatory support for certain products and regions.* Under our 2006 agreements, we will take on worldwide responsibility for regulatory activities regarding the INTERCEPT Blood System, except in territories covered by our agreement with BioOne for the platelet and plasma systems, provided that Baxter remains as the registrant or applicant under European registrations and applications for a transition period in 2006. We do not currently have the appropriate resources to support regulatory activities relating to these products. We currently lack the resources and capabilities to respond appropriately to customer complaints or required regulatory reporting of adverse events arising from the use of the platelet system. We will need to increase our regulatory resources or contract with independent regulatory consultants, which may result in increased costs and may potentially delay regulatory filings. Delays or inabilities to complete regulatory filings and obtain approvals will also delay or prevent us from earning milestone payments from BioOne, and from being able to recognize sales of our products and attaining profitability. Our agreements with Baxter require that Baxter transfer to us European regulatory registrations for the platelet system and European regulatory applications for the platelet and plasma systems once we have obtained necessary regulatory certification of our quality systems. An audit of our quality systems by European regulators is a

prerequisite to such regulatory certification. Any delay in obtaining such certification would result in a delay in obtaining regulatory approval of the plasma system in Europe and may have other adverse consequences. There may be unforeseen adverse consequences in making this transition if regulatory agencies view the change negatively, which in turn may lead to potential delays in approvals.

We will continue to rely on Baxter for manufacturing and supplying components of our platelet and plasma systems for a limited period of time. We are also relying on Baxter to complete certain development activities relating to the plasma system. Over a longer period, we will need to identify, select and qualify third party sources of supply for the INTERCEPT Blood System, including the INTERCEPT red blood cell system.

- *We currently rely on Baxter for manufacturing and supplying components of our systems.* Under the terms of our agreements, Baxter is currently responsible for manufacturing and supplying certain components and devices of the INTERCEPT Blood System for development and commercial use through 2008. If Baxter fails to manufacture and supply an adequate supply of components or devices, we will be required to identify other component manufacturers. We may be unable 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 components from Baxter could delay further regulatory approvals, 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. Baxter manufactures our platelet and plasma systems and only limited components for our red blood cell system in facilities that are not FDA-approved. Our agreements do not require Baxter to validate these manufacturing facilities with the FDA. In order to be sold in the United States, our systems would be required to be manufactured in an FDA-approved facility. FDA validation of a manufacturing facility, whether owned by Baxter or by another party, will be costly and time-consuming. Because of low sales volumes and other reasons, Baxter's costs to manufacture commercial components for the platelet system are greater than we previously anticipated and may continue to rise. This will reduce our potential gross profit margin from European platelet system sales. Under the terms of our agreements, Baxter has committed to conduct certain development activities for the plasma system that are necessary for CE mark approval of the disposable set and CE mark self-declaration for the UVA illuminator. If such activities are not completed in a timely manner, our CE mark submission and self-declaration for the plasma system will be delayed.
- *Baxter may assign its agreements with us to third parties* . It has been reported that Baxter is seeking to sell the business unit that performs Baxter's obligations under our agreements. We do not control, and cannot predict, whether, when or to whom the business unit may be sold. The business unit may be sold to an existing industry participant, including a strategic partner or a competitor, or to a private equity firm. While the assignment provision of our February 2006 agreement provides that the agreement may be assigned only to an assignee that assumes all of Baxter's obligations under the agreement and has capability to perform the obligations, the acquirer of the business unit may fail to manufacture or supply an adequate supply of components or devices of the INTERCEPT Blood System, which would subject us to the risks described above. All references to "Baxter" in these Risk Factors should be read, as to future contingencies, to include any assignee of Baxter's obligations under our agreements.
- *We will be required to identify and enter into agreements with third parties to manufacture the INTERCEPT Blood System products and related blood component storage solutions.* Baxter's manufacturing responsibilities for certain components of the platelet and plasma systems in general extend through 2008, after which we will assume manufacturing responsibilities. Except for very limited manufacturing of disposable components, Baxter is no longer obligated to provide manufacturing services related to the INTERCEPT red blood cells system, or red blood cell system, at all. We will need to identify parties to provide those manufacturing services related to our red blood cell system at all. It may be difficult to enter into these types of agreements on reasonable terms. In particular, it will be time-consuming for other manufacturers to develop the capability to manufacture the INTERCEPT

Blood System products and blood component storage solutions economically and to gain regulatory approval to do so for commercial use. We may be unable to identify and contract with manufacturers that can make our products cost-effectively, which would delay our efforts to commercialize our products.

The platelet system is not compatible with platelet collection platforms and platelet storage solutions manufactured by others.

The equipment and materials used to collect platelets vary from manufacturer to manufacturer. Our system for platelets is designed to work with platelets collected using a proprietary platelet storage solution, called Intersol, and, for platelets collected by apheresis, is fully compatible only with Baxter's apheresis platelet collection system. We have conducted our clinical studies for the platelet system using only Baxter's equipment and materials. Baxter may not make its apheresis collection system available for sale in certain countries and has elected to discontinue sales efforts for its apheresis collection system in Japan. Under an agreement with Haemonetics Corporation, or Haemonetics, Baxter has agreed to provide Haemonetics with Intersol, with the objective that platelets collected on certain Haemonetics apheresis collection equipment may be directly treated using our platelet system. Making the Haemonetics apheresis collection system readily compatible with our platelet system will require certain changes in the Haemonetics device, and there can be no assurance that Haemonetics will undertake this effort on a timely basis or be commercially successful. Gambro, Inc., or Gambro, another major supplier of automated platelet collection systems, is conducting clinical trials of its own system for pathogen inactivation of platelets. For competitive reasons, Gambro may have little or no incentive to make its apheresis collection system compatible with our platelet system. Attaining compatibility with collection platforms and platelet storage solutions manufactured by others would require adaptations to either our platelet system or to the collection platforms, which may be difficult to engineer, expensive to implement and test, require additional clinical trials, cause delays in regulatory approval and/or be commercially unattractive to pursue. These development activities will increase our costs significantly, and may not be successful. Market acceptance of the platelet system in the United States and other countries may be delayed until the system receives regulatory approval for use on such other equipment.

Because the INTERCEPT Blood System products have not been manufactured on more than a limited commercial scale, we face manufacturing uncertainties that could limit their commercialization. If our third-party manufacturers fail to produce our products or compounds satisfactorily and in sufficient quantities, we may incur delays, shortfalls and additional expenses, which may in turn result in permanent harm to our customer relations.

The INTERCEPT Blood System products, 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 to be used in our products. These compounds have not yet been produced in quantities sufficient to support commercialization for all regions in which we may market our products. We have an agreement with a manufacturer to produce commercial quantities of amotosalen, a proprietary compound used in our platelet and plasma systems. We currently do not have any third-party manufacturing agreements in place for commercial production of compounds used in our red blood cell system. 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 platelet and plasma systems and Intersol products through 2008. Baxter relies 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 produced some pathogen inactivation systems in modest commercial quantities, but may not be able to manufacture and assemble other systems or in larger quantities, or do so economically. If Baxter (or Cerus after

2008) or our third-party manufacturers fail to produce our products or Intersol products satisfactorily and in sufficient quantities, we may incur delays, shortfalls and additional expenses, which may in turn result in permanent harm to our customer relations. 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.

Baxter purchases 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. It would be expensive and time-consuming to establish additional or replacement suppliers for these components. If Baxter (or Cerus after 2008) is 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 will continue to rely on Baxter for transition services. Over a longer period, we will need to perform these services ourselves or identify one or more alternative third party providers.

Under the terms of our February 2006 agreement, Baxter is required to provide certain transition services relating to European activities, at our expense. These services included specified regulatory and clinical support activities, installation, maintenance and calibration services until December 31, 2006, clinical education and training until December 31, 2006 and manufacturing technical information and advice until December 31, 2008. If Baxter fails to provide these services, we may be unable to assume these functions ourselves or identify alternative third party providers on a timely basis or on reasonable terms, if at all. Any delay in these activities could delay further regulatory approvals, market introduction and subsequent sales of the systems.

We have used prototype components in our preclinical studies and clinical trials in the United States and have not completed the components' commercial design.

The system disposables and instruments we used in many of our preclinical studies and clinical trials in the United States were prototypes of those to be used in the final products. As a result, we plan to perform studies, both preclinical and clinical, to demonstrate the acceptability of the commercial configuration and the equivalence of the prototypes and the commercial products' design. However, regulatory authorities may require us to perform additional studies, both preclinical and clinical, using the commercial versions of the systems, which may increase our expenses and delay the commercialization of our products. If we fail to develop commercial versions of the INTERCEPT Blood System on schedule, our potential revenue would be delayed or diminished and our competitors may be able to bring products to market before we do.

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 rely on BioOne for commercialization of our platelet and plasma systems in many Asian countries.

Baxter and we have licensed rights to commercialization of the platelet and plasma systems in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore to BioOne. BioOne is solely responsible for obtaining regulatory approvals, marketing and selling the platelet and plasma systems in those countries. Because we only have a minority investment interest in BioOne, we lack the ability to significantly influence BioOne, and are dependent on BioOne's performance to realize milestone and royalty revenue from commercialization of our platelet and plasma systems in those countries. In Japan, regulatory authorities may require a product to be approved by the FDA before it is considered for approval in Japan, which would delay or prevent BioOne from

achieving significant product sales. If BioOne is not successful, we will not receive milestone or royalty revenue derived from platelet or plasma system sales in those countries and the value of our equity in BioOne may be lost. There is no assurance that BioOne will be able to attract additional required capital to successfully commercialize those products licensed from Baxter and us.

If our competitors develop and market products that are more effective than our product candidates or fail in human clinical trials, our commercial opportunity will be reduced or eliminated.

We expect our products to encounter significant competition. The INTERCEPT Blood System products may compete with other approaches to blood safety currently in use, as well as with future products developed by others. Our success will depend in part on our ability to respond quickly to medical and technological changes brought about by 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. In addition, competitors or potential competitors may have substantially greater financial and other resources than we have. They may also have greater experience in preclinical testing, human clinical trials and other regulatory approval procedures.

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 pathogen inactivation systems to treat fresh frozen plasma. Navigant, a wholly owned subsidiary of Gambro, is developing a pathogen inactivation system for blood products.

New methods of testing blood for specific pathogens have been approved by the FDA and in Europe, as have tests for bacteria in platelets. Continued delays in commercialization of the platelet system in France and Germany may impact our ability to compete with bacterial testing for platelets. Tests have now been approved to detect West Nile Virus in blood products. Other groups are developing synthetic blood product substitutes and products to stimulate the growth of platelets. Development of any of these technologies could impair the potential market for our products.

There are many companies pursuing programs for the treatment of cancer and treatment and prevention of infectious disease. Some are large pharmaceutical companies, such as Sanofi-Aventis, Bristol-Myers Squibb, Genentech and Gilead, which have greater experience and resources in product development, preclinical testing, human clinical trials, obtaining FDA and other regulatory approvals and in manufacturing and marketing new therapies. We are also competing with other biotechnology companies, such as Cell Genesys, Inc., Coley Pharmaceutical Group, Dendreon Corporation, and Therion Biologics Corporation that have cancer vaccine programs that are in more advanced stages of development than ours. In addition, other companies are pursuing early-stage research and development of *Listeria* -based immunotherapies. If any of these companies' products are shown to be more efficacious than ours, our *Listeria* -based products may fail to gain regulatory approval or commercial acceptance. If these companies' products fail in human clinical trials, we may be required to overcome more significant regulatory barriers prior to gaining approval, face more challenging impediments to market acceptance and may be unable to raise capital to fund development of our *Listeria* programs.

We may be liable if our products harm people. We may be liable if an accident occurs in our controlled use of hazardous materials.

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and pharmaceutical products. We may be liable if any of our products cause injury, illness or death. Although we will have completed rigorous preclinical and clinical safety testing prior to marketing our products, there may be harmful effects caused by our products that we are unable to identify in preclinical or clinical testing. In

particular, unforeseen, rare reactions or adverse side effects related to long-term use of our products may not be observed until the products are in widespread commercial use. 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.

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.

We operate from a single site that is subject to lengthy business interruption in the event of a severe earthquake.

Our facilities are all based in Concord, California and are within an active earthquake fault zone. Should a severe earthquake occur, we might be unable to occupy our facilities or conduct research and development activities in support of our products until such time as our facilities could be repaired and made operational. Our property and casualty and business interruption insurance in general does not cover losses caused by earthquakes. While we have taken certain measures to protect our scientific, technological and commercial assets, a lengthy or costly disruption due to an earthquake would have a material adverse effect on us.

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 $58.3 million in 2003, $31.2 million in 2004. However, in 2005, we realized a $22.1 million gain associated with the restructuring of a loan payable. As a result of this gain, we recorded net income of $13.1 million in 2005. At December 31, 2005, we had an accumulated deficit of approximately $306.6 million. Except for the platelet system, which has received European 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 our 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 more of our product candidates are commercialized and achieve significant market acceptance.

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

Our product development programs are capital-intensive. We may need to reduce or stop further investment in specific research and development or sales and marketing activities if we are unable to obtain additional capital or if any of our development programs are determined by us to be economically unfeasible. A product or program may be determined to be uneconomic if the commercial opportunity is insufficient to justify the investment required to develop and market the product or for other reasons. We expect that our spending in support of research, development and commercialization of the platelet and plasma systems will be in excess of contribution from product sales, milestone payments and development funding for such programs from third parties over the next year. We have recently elected to re-enter clinical trials for the red blood cell system with only partial funding from governmental sources. In addition, the 2006 restructuring agreement with Baxter requires that we take on more operational and financial responsibility for the commercialization of the platelet and plasma systems, particularly in Europe. As a result of these factors, further product development and commercialization of the INTERCEPT Blood System may take longer and be more expensive than we previously

anticipated. We expect to continue to spend substantial funds for our operations for the foreseeable future. Our cash, liquidity and capital requirements will depend on many factors, including the development progress and costs of our programs, payments by MedImmune, BioOne and others, funding from agencies of 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.

As of December 31, 2005, we had been awarded $33.8 million in funding under cooperative agreements with the Department of Defense, and also have received funding under grants from the National Institutes of Health. Further funding awarded under federal grants and cooperative agreements is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U.S. Congress. If we are unable to obtain federal grant and cooperative agreement funding for future activities at similar or greater levels, we may need to further reduce our operating expenses, which would delay progress in some of our development programs. In addition, we are required separately to administer and account for our work under government contracts and grants on an on-going basis as a condition to accepting government funding which places administrative, accounting and reporting burdens on us beyond those we have assumed as a public company. If we fail to comply with applicable governmental administrative, accounting and reporting regulations with respect to these grants and cooperative agreements, funds currently available to us may be reduced or lost.

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.

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. In addition, others hold patents, and have pending patent applications, concerning *Listeria* -based immunotherapies. Those patents and new patents that may be issued upon the pending applications, if valid, would restrict us from bringing to market particular embodiments of *Listeria* -based immunotherapy products. While we believe that such restrictions do not preclude us from developing and commercializing our *Listeria* -based immunotherapy products, they may preclude us from pursuing certain product approaches that might otherwise be promising. Our patents expire at various dates between 2009 and 2018. Recent patent applications, principally related to our immunotherapy programs, will, if granted, result in patents with later expiration dates. 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 before 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. These agreements may be breached and 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 also may arise as to the rights in related or resulting know-how and inventions.

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, 2003 to December 31, 2005, the sale price of our common stock as quoted on the Nasdaq National Market fluctuated from a low of $1.60 to a high of $21.75. 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;
- dilution from future issuances of common stock;
- 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 current and former 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. In addition, our directors and certain of our current and former officers have been named as defendants in a derivative lawsuit in the Superior Court for the County of Contra Costa, California, 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.

We may fail to comply fully with elements of the Sarbanes-Oxley Act of 2002. Our failure to maintain effective internal controls in accordance with Section 404 of this Act could have a material adverse effect on our stock price.

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accountants attesting to and reporting on these assessments. If we fail to maintain the adequacy of our internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude in future periods that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. If we cannot favorably assess, or our independent registered public accountants are unable to provide an unqualified attestation report on our assessment of, the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

We lease approximately 21,400 square feet for our main office facility in Concord, California. The lease for this facility extends through July 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 31,800 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 2010 and October 2006, respectively. Our 9,900 square foot facility contains three one-year renewal options and our 31,800 square foot facility contains five 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 December 8, 2003, a class action complaint was filed in the United States District Court for the Northern District of California against certain of our current and former directors, officers and us. The complaint alleges that the defendants violated the federal securities laws by making certain alleged false and misleading statements regarding the compound used in our red blood cell system. 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. On May 24, 2004, the plaintiffs filed a consolidated complaint. The consolidated complaint abandons the allegations raised in the original complaints. Instead, the plaintiffs claim that the defendants issued false and misleading predictions regarding the initiation and completion of clinical trials, submission of regulatory filings, receipt of regulatory approval and other milestones in the development of the platelet, plasma and red blood cell systems. The consolidated complaint retains the same class period alleged in the original complaints. On June 17, 2004, the plaintiffs filed an amended consolidated complaint substantially similar to the previous consolidated complaint with additional allegations attributed to a confidential witness. On July 20, 2004, the defendants moved to dismiss the amended consolidated complaint. On January 20, 2005, the Court dismissed the complaint with leave to amend within 60 days. On March 21, 2005, the plaintiffs filed a second amended consolidated complaint, and on May 24, 2005, the plaintiffs filed a third amended consolidated complaint. The allegations of both the second and third amended consolidated complaints were similar to those contained in the previous amended consolidated complaint. On July 8, 2005, the defendants moved to dismiss this third amended consolidated complaint. We believe that this matter will not have a material effect on our results of operations or financial position; however, we cannot predict the outcome of this litigation.

On December 15, 2003, our directors and certain of our current and former 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. A virtually identical derivative complaint was filed on March 17, 2004 in the same Court. The plaintiffs in these actions are Cerus stockholders who seek to bring derivative claims on behalf of Cerus against the defendants. The lawsuit alleges breach of fiduciary duty and related claims. On June 1, 2004, the plaintiffs filed a consolidated complaint. The consolidated complaint repeats the allegations made in the original complaints, asserts the same claims as those complaints and seeks an unspecified amount of damages. On August 5, 2004, the Court approved a stipulation and proposed order staying the action for so long as the discovery stay in the securities action remains in place. The order further provides that plaintiffs may file an amended consolidated complaint within thirty days following the resolution of the pleadings in the securities action. We believe that this matter will not have a material effect on our results of operations or financial position; however, we cannot predict the outcome of this litigation.

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

None.

PART II

Item 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

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, 2004:		
First Quarter	$ 4.95	$3.32
Second Quarter	5.50	2.10
Third Quarter	2.73	1.60
Fourth Quarter	3.30	2.21
Year Ended December 31, 2005:		
First Quarter	5.08	2.93
Second Quarter	4.75	3.04
Third Quarter	9.23	4.27
Fourth Quarter	$11.63	$6.46

On February 17, 2006, the last reported sale price of our common stock on the Nasdaq National Market was $12.98 per share. On February 17, 2006, we had approximately 223 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, 2005. 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.

	2005	2004	2003	2002	2001
		(In thousands, except per share data)			
Statement of Operations Data:					
Revenue	$ 24,371	$ 13,911	$ 9,665	$ 8,490	$ 4,535
Operating expenses:					
Research and development	24,134	27,651	52,484	56,421	48,247
General and administrative	9,578	10,225	11,016	11,346	10,166
Restructuring	—	2,861	—	—	—
Total operating expenses	33,712	40,737	63,500	67,767	58,413
Loss from operations	(9,341)	(26,826)	(53,835)	(59,277)	(53,878
Net interest and other income (expense)	22,405	(4,327)	(4,432)	2,085	4,611
Income (loss) before income taxes	13,064	(31,153)	(58,267)	(57,192)	(49,267)
Provision for income taxes	—	—	—	—	(100)
Net income (loss)	$ 13,064	$ (31,153)	$ (58,267)	$ (57,192)	$ (49,367)
Net income (loss) per common share-(1):					
Basic	$ 0.58	$ (1.41)	$ (3.01)	$ (3.61)	$ (3.27)
Diluted	$ 0.55	$ (1.41)	$ (3.01)	$ (3.61)	$ (3.27)
Weighted average common shares outstanding used for basic and diluted income (loss) per common share: (1)					
Basic	22,350	22,143	19,367	15,833	15,105
Diluted	23,950	22,143	19,367	15,833	15,105

	2005	2004	2003	2002	2001
			(In thousands)		
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 45,805	$ 95,334	$ 110,010	$ 64,318	$ 123,461
Working capital	27,690	23,782	49,819	50,486	108,606
Total assets	58,660	102,078	118,463	72,947	128,260
Loan and interest payable	4,826	39,000	55,834	—	—
Capital lease obligations, less current portion	68	—		16	51
Redeemable convertible preferred stock	—	—	—	—	5,000
Accumulated deficit	(306,643)	(319,707)	(288,554)	(230,287)	(173,095)
Total stockholders' equity	$ 35,275	$ 21,489	$ 52,528	$ 56,169	$ 106,755

(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 blood safety systems and, more recently, immunotherapies for cancer and infectious disease. With the exception of a non-recurring gain recognized in 2005, we have been generally unprofitable since inception and, as of December 31, 2005, had an accumulated deficit of approximately $306.6 million. Except for the platelet system, for which the European Union approved issuance of a CE mark, all of our product candidates are in the research and development stage. In late 2005, we filed an IND for CRS-100, a product candidate employing our attenuated *Listeria* technology platform, and we have elected to re-enter Phase I human clinical trials in the United States for the red blood cell system, which we plan to initiate in 2006. Our primary source of revenue is from milestone and development funding from our collaborative partners and we have not received significant revenue to date from product sales. We must conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities on our 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 commercialize and achieve market acceptance of our immunotherapy and blood safety product candidates. We may never achieve a profitable level of operations.

We currently derive a significant portion of our revenue from an ongoing development agreement with MedImmune and commercialization agreements with BioOne. Under the agreements with MedImmune and BioOne, we are receiving development funding and may receive contingent milestone payments and royalties on future product sales. As of December 31, 2005, we have received $1.5 million of upfront and milestone payments from MedImmune under the terms of the agreement, consisting of a $1.0 million up front payment and a $0.5 million milestone payment, and have received a total of $15.0 million in cash payments and equity securities from BioOne. We are also receiving development funding from MedImmune and recognized $2.4 million and $1.6 million of development funding during the years ended December 31, 2005 and 2004, respectively. We also entered into cooperative agreements with the Armed Forces of the United States to conduct certain research and development activities, and we recognized $10.6 million under funding awards received in connection with these agreements during the year ending December 31, 2005. Of the $10.6 million recognized under the Armed Forces agreements during the year ending December 31, 2005, $4.1 million related to our blood safety programs and $6.5 million related to our immunotherapy programs.

We recently discontinued a collaboration with the Pharmaceutical Division of Kirin Brewery Co. Ltd. under which we were developing and marketing products for stem cell transplantation. We recognized approximately $0.3 million in deferred revenue in the period ending December 31, 2005, that would have been recognized in future periods had the collaboration continued.

Effective February 1, 2006, we entered into a new agreement with Baxter related to the INTERCEPT Blood System. Under terms of the 2006 agreement, we gained worldwide rights to the INTERCEPT platelet and plasma systems previously held by Baxter, excluding certain Asian countries covered in agreements with BioOne. We previously acquired worldwide commercialization rights for the red blood cell system from Baxter. We will pay Baxter royalties on future product sales, with a rate of 10% of net sales for the platelet system, 3% for the plasma system and 5% for the red blood cell system. The payment of royalties replaces the terms of previous agreements in which we received a defined share of gross profit from product sales. Under the terms of the February 2006 agreement, Baxter has agreed to supply certain transition services to us in 2006 at our expense, including

regulatory, technical and back-office support, and to conduct certain continued development efforts relating to the plasma system at its expense. For the year ended December 31, 2005, we applied $1.2 million of Baxter's $13.1 million commitment to expenses we incurred during the period in preparing an application for CE mark approval of the plasma system, which was recognized as development funding revenue.

We will record gains and deferred gains of approximately $6.5 million in the period ending March 31, 2006, resulting largely from the disbursement to us of funds that remain from the $13.1 million commitment described above. In February 2006, we also repaid the $4.5 million promissory note plus accrued interest owed to Baxter Capital that had originally been due in December 2006.

Under the terms of February 2006 agreement, we are responsible for the commercialization and development of the platelet and plasma systems, except in parts of Asia, and we expect that our spending over the next year in support of research, development and commercialization of the platelet and plasma systems will be in excess of the contribution from product sales to customers and from milestone payments and development funding for such programs from Baxter, BioOne, the Armed Forces of the United States, or Armed Forces, and others. We also anticipate increasing our expenditures in support of clinical trials and device development of our red blood cell system, as well as the preclinical and early stage clinical development of our immunotherapy programs in both cancer and infectious disease.

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, preclinical safety studies, external laboratory studies and development activities performed by Baxter. 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. To date we have not received license fees or milestone payments that are refundable. To the extent that they are subject to future performance criteria, we recognize as revenue ratably over the estimated license or development period. We have received up-front payments from collaboration agreements. These up-front payments are deferred and recognized over the period to which the payments relate. 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.
- Short-term 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 re-evaluate 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, preclinical 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.

Results of Operations

2005 Compared with 2004

Revenue. For the year ended December 31, 2005, milestone and development funding, which includes amounts received from Baxter, BioOne, MedImmune and Kirin, increased 179% to $11.7 million from $4.2 million for 2004. The increase was primarily due to revenue recognized from up-front payments received from BioOne and MedImmune that were deferred in 2004 and are being recognized ratably over respective development terms, increased development funding and a milestone payment received from MedImmune under the April 2004 agreement. Milestone and development funding from Baxter, BioOne, MedImmune and Kirin was 14%, 62%, 21% and 3%, of milestone and development revenue respectively for the year ended December 31, 2005.

Revenue from government grants and cooperative agreements increased 26% to $12.2 million in the year ended December 31, 2005, from $9.7 million for 2004, due primarily to increased government funding for both blood safety and vaccines programs.

For the year ended December 31, 2005, we recognized $0.5 million of product sales revenue from our share of sales of the platelet system in Europe. As a result of a loan dispute with Baxter Capital that was subsequently resolved, we also recognized approximately $0.2 million in product sales revenue from 2004 that was deferred until February 2005. The platelet system is currently undergoing experience studies, regulatory review and reimbursement review in many European countries. We do not expect sales of the platelet system in Europe to significantly change until at least the platelet system is approved for sale and reimbursement levels are established in the larger-market European countries.

Research and Development Expenses. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, payments for licensed technologies, 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, preclinical safety studies, manufacturing development and other laboratory studies. Research and development expenses decreased 13% to $24.1 million in the year ended December 31, 2005, from $27.7 million for 2004. Increased spending on vaccines programs, particularly in support of development of CRS-100 and CRS-207, was offset by reduced spending for our blood safety programs. Our total research and development costs included $11.0 million for our blood safety programs and $13.1 million for our immunotherapy programs for the year ended December 31, 2005, and $17.9 million for our blood safety programs and $9.8 million for our immunotherapy programs for the comparable period in 2004.

We anticipate that our research and development expenses for 2006 will increase relative to 2005, primarily as a result of our entering Phase I clinical trials with CRS-100 and the red blood cell system, as well as conducting more extensive preclinical studies for CRS-207. Due to the inherent uncertainties and risks associated with developing biomedical and biopharmaceutical products, including but not limited to intense and changing government regulation, uncertainty of future preclinical 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 6% to $9.6 million for the year ended December 31, 2005, from $10.2 million for 2004, due principally to reduced headcount costs

in 2005 which result from the 2004 restructuring of our operations. We expect general and administrative expenses will rise modestly for our domestic operations in 2006, primarily reflecting increased headcount in functions supporting both our blood safety and vaccines programs. We expect to incur modest incremental selling, general and administrative costs in Europe as a result of the February 2006 restructured agreements with Baxter.

Restructuring. On June 30, 2004, we announced that we realigned our operations to better match our cost structure to our operations. As a result of the realignment, we reduced our workforce by approximately 35% and reduced our operating expenses. We recorded aggregate charges of $2.9 million during the second and third quarters of 2004 related to this restructuring. Restructuring costs primarily include severance benefits to employees terminated as part of the restructuring. We do not expect to record further costs related to the 2004 restructuring.

Gain on Loan Settlement. Concurrent with the 2005 restructured agreements between Baxter and us, Baxter Capital and we entered into an agreement under which we immediately paid $34.5 million to Baxter Capital and entered into a promissory note for $4.5 million, payable with 8% interest in December 2006. Baxter Capital agreed to accept these payments in full satisfaction of the loan obligation, and the parties dismissed all related legal actions. As a result, we recorded a non-operating gain of $22.1 million that reflected the difference between loan principal and accrued interest balances recorded through 2004, less amounts paid in February 2005 and remaining accrued liabilities as a result of the settlement, and long-term debt of $4.5 million, representing the note due to Baxter Capital in December 2006, which accrues interest at 8%. The gain on the loan settlement was recognized in the period ending March 31, 2005, when the settlement occurred.

As a result of the February 2006 agreement with Baxter, we will record gains and deferred gains of approximately $6.5 million in the period ending March 31, 2006, resulting largely from the disbursement of escrow funds that remain from the $13.1 million commitment from Baxter associated with the 2005 restructured agreements. Also as a result of the 2006 agreement, we repaid the $4.5 million promissory note plus accrued interest owed to Baxter Capital that was originally due in December 2006.

Net Interest and Other Income/(Expense). Net interest and other income was $22.4 million for the year ended December 31, 2005, compared to net interest and other expense of $4.3 million for 2004. Net interest and other income for the year ended December 31, 2005 includes the $22.1 million gain realized under the 2005 Baxter restructured agreement as discussed in the preceding paragraph. The change in net activity of $26.7 million is primarily the result of the repayment of $34.5 million to Baxter under the terms of a loan dispute settlement with Baxter in February 2005, offset by slightly lower interest income. Net interest income was $1.1 million and $1.6 million for the year ended December 31, 2005, and 2004, respectively. The reduced interest income in 2005 compared to 2004 was due to lower investment account balances. We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain. In 2005, interest was accrued at 8% on the $4.5 million note payable to Baxter Capital. In 2004, interest was accrued at 12.0% on the $50.0 million loan from Baxter Capital.

2004 Compared with 2003

Revenue. For the year ended December 31, 2004, milestone and development funding from Baxter increased 100% to $0.8 million from $0.4 million for 2003. The increase was primarily due to the termination of the Phase III clinical trials for the red blood cell system in September 2003, for which Baxter was incurring greater expenses than us. 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. Development funding from Baxter was 5% of total revenue for 2004.

Development funding from other sources, which included MedImmune, BioOne, Kirin and the NMDP, increased to $3.4 million for 2004 from $0.6 million for 2003. The increase was primarily due to development

funding from MedImmune and from up-front payments received from MedImmune and BioOne that were deferred and are being recognized ratably over the respective development periods.

Revenue recognized from Kirin in 2004 and 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 agreement with the NMDP expired on March 31, 2004. Development funding from MedImmune, BioOne, Kirin and the NMDP was 11%, 12%, 1% and less than 1%, respectively, of total revenue for 2004.

Revenue from government grants and cooperative agreements increased 13% to $9.7 million for 2004 from $8.6 million for 2003. The increase was primarily due to increased program expenditures under the cooperative agreements with the Armed Forces, largely in support of research and development applicable to the INTERCEPT Blood System for plasma. During 2004, we also recognized $0.9 million of revenue from eight separate research grants from the National Institutes of Health, including amounts recognized under a $3.8 million grant to develop an anthrax vaccine. We may not receive additional government grants in the future.

We recognized $0.1 million of product sales revenue in 2003 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 2004 was deferred and recognized in the first quarter of 2005, when payment of such revenue was collected from Baxter.

Research and Development Expenses. Research and development expenses decreased 47% to $27.7 million for 2004 from $52.5 million for 2003. The decrease was primarily due to reduced development spending by Baxter, the termination of Phase III clinical trials in the red blood cell program in September 2003 and our June 2004 restructuring. Our total research and development costs for 2004 included $17.9 million for the INTERCEPT Blood System program and $9.8 million for all other programs, including vaccine programs, while research and development costs in 2003 included $45.6 million for the INTERCEPT Blood System program and $6.9 million for all other programs.

General and Administrative Expenses. General and administrative expenses decreased 7% to $10.2 million for 2004 from $11.0 million for 2003. The decrease was primarily due to fewer administrative personnel and consultants in 2004 as a result of our June 2004 restructuring.

Restructuring. On June 30, 2004, we announced that we realigned our operations to better match our cost structure to our operations. As a result of the realignment, we reduced our workforce by approximately 35% and reduced our operating expenses. We recorded aggregate charges of $2.9 million during the second and third quarters of 2004 related to this restructuring. Restructuring costs primarily include severance benefits to employees terminated as part of the restructuring.

Net Interest and Other Income/(Expense). Net interest and other income (expense) was $4.3 million of net expense for 2004, down slightly from $4.4 million of net expense in 2003. In 2004 and 2003, we accrued interest expense at 12% on the $50.0 million loan from Baxter Capital. Interest expense accrues at 8% on a $4.5 million note payable to Baxter Capital. Interest income from investments was $1.6 million for 2004 compared to $1.5 million for 2003. The change was primarily due to more favorable yields on investments as a result of increases in market interest rates.

Liquidity and Capital Resources

Our sources of capital to date have primarily consisted of public offerings, private placements of equity securities, loans from Baxter Capital, payments received under our agreements with Baxter, BioOne, MedImmune and others, 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 additional products receive regulatory approval and achieve market acceptance.

At December 31, 2005, we had cash, cash equivalents and short-term investments of $45.8 million. Net cash used in operating activities was $14.9 million in 2005, compared to $12.7 million in 2004. Cash used in our operating activities during 2005 was impacted by the increase in our deferred revenues mainly due to agreements with BioOne and changes in other operating assets and liabilities, offset by net income of $13.1 million.

Net cash provided by investing activities of $15.4 million resulted primarily from sales and maturities of short-term investments exceeding the purchases of short-term investments and capital improvement made during the year. Working capital increased to $27.7 million at December 31, 2005, from $23.8 million at December 31, 2004, primarily due to the settlement of the loan dispute with Baxter Capital in 2005.

In February 2005, we entered into an agreement with Baxter Capital under which we paid $34.5 million to Baxter Capital and entered into a promissory note for $4.5 million, payable with 8% interest in December 2006. Baxter Capital agreed to accept these payments in full satisfaction of the $50.0 million loan and accrued interest under the previous loan obligation, and the parties agreed to dismiss all related legal actions. Pursuant to the terms of the 2006 agreements with Baxter, we agreed to immediately repay the $4.5 million promissory note and accrued interest to Baxter Capital upon receipt of a disbursement from Baxter representing remaining funds held in escrow from Baxter's $13.1 million allotment for commercialization of the platelet and plasma systems in Europe, less certain specified amounts.

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 at least through at least mid-2007. These near-term capital requirements are dependent on various factors, including the development progress and costs of the INTERCEPT Blood System and our therapeutic vaccine programs, payments from our development and commercialization partners, including MedImmune and BioOne, and from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will be dependent on these factors and on 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, development progress in our vaccine programs, regulatory approval and successful commercialization of the INTERCEPT Blood System and other product candidates, competitive developments and regulatory factors. 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 $300.0 million of common stock and/or debt securities. In June 2003, we completed a public offering of 6.0 million shares of common stock with gross proceeds of $57.8 million under the shelf registration statement. We may raise additional capital by selling securities at any time, though we have no current commitments to offer or sell additional securities pursuant to this registration statement.

Commitments

The following is a summary of our contractual obligations as of December 31, 2005 (in thousands):

	Payments Due by Period, from December 31, 2005				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Contractual obligations:					
Loan and interest payable	$5,181	$ 5,181	$ —	$ —	$ —
Minimum purchase requirements	250	50	100	100	—
License fees and sponsored research	666	425	88	63	90
Operating leases	2,549	1,123	1,110	316	—
Total contractual cash obligations	$8,646	$ 6,779	$1,298	$ 479	$ 90

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

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments in our investment portfolio. By policy, we place our investments with high quality debt security issuers, limit the amount of credit exposure to any one issuer and limit duration by restricting the term for single securities and for the portfolio as a whole.

The table below presents the amounts and weighted interest rates of our cash equivalents and marketable securities at December 31, 2005 (dollar amounts in thousands):

	Fair Value	Weighted Average Interest Rate
Cash equivalents (0 – 90 days)	$ 5,062	4.04%
Short-term investments (91 days – 1 year)	—	—
Short-term investments (1 – 3 years)	39,730	2.62%
Total investments	$ 44,792	

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

Our financial statements, together with related notes and reports of Ernst & Young LLP, independent registered public accounting firm, 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, 2005, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in this Annual Report on Form 10-K was (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and (ii) accumulated and communicated to our management, including our principal executive and principal financial officers, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting. During the last quarter of our fiscal year ended December 31, 2005, there were no 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 chief financial officer have concluded that these controls and procedures are effective at the "reasonable assurance" level.

Management's Assessment of Internal Control. Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005, is discussed in the Management's Report on Internal Control Over Financial Reporting included on page 45.

Item 9B. ***Other Information***

2005 Executive Bonuses. The Compensation Committee of our Board of Directors awarded the following bonuses to our executive officers in connection with the achievement in fiscal year 2005 of specified corporate milestones and individual goals:

Executive Officer	Position	Cash	Fair Value of Restricted Stock Units Subject to Vesting [1]	Total
Claes Glassell	President and Chief Executive Officer	$305,850	$ 109,650	$415,500
David N. Cook	Vice President, Research and Development	$ 97,125	$ 41,625	$138,750
Laurence M. Corash	Vice President, Medical Affairs	$ 94,938	$ 40,687	$135,625
Howard G. Ervin	Vice President, Legal Affairs	$128,829	$ 33,784	$162,613
William J. Dawson	Vice President, Finance and Chief Financial Officer	$ 94,209	$ 31,804	$126,013

1 Fair value of Restricted Stock Units Subject to Vesting based on closing price of common stock on January 6, 2006.

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, or proxy statement, for use in connection with the annual meeting of stockholders to be held on June 6, 2006, 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 2005 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.

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PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

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

(a) *Financial Statements* .

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

(b) 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.
10.44(14)†	Collaboration and License Agreement, dated April 20, 2004, between Cerus Corporation and MedImmune, Inc.
10.45(14)*	Employment Agreement, dated August 5, 2004, between Cerus Corporation and Claes Glassell.
10.46(15)*	Employment Agreement, dated July 22, 2004, between Cerus Corporation and William J. Dawson.
10.47(a)*	Bonus Plan for Senior Management of Cerus Corporation, dated April 1, 2003, as amended on December 9, 2004, January 18, 2005, and February 15, 2005.
10.48(16)†	Amendment, Mutual Release and Settlement Agreement, dated as of February 2, 2005, between Cerus and Baxter Capital Corporation.
10.49(16)	Amended and Restated Note, dated as of February 3, 2005, payable to the order of Baxter Capital Corporation.
10.50(16)†	Restructuring Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.

10.51(16)†	License Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.52(16)†	Manufacturing and Supply Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
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.
(a) Previously filed.
(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.
(14) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.
(15) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.
(16) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management is responsible for establishing and maintaining effective internal control over the Company's financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2005. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control—Integrated Framework* . Based on this assessment, management has concluded that, as of December 31, 2005, the Company's internal control over financial reporting is effective.

The Company's independent registered public accounting firm, Ernst & Young LLP, has audited management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2005. Ernst and Young's attestation report on management's assessment of internal control over financial reporting is included at page 46.

The Company's internal control system was designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM, ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The Board of Directors and Stockholders of Cerus Corporation

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Cerus Corporation maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Cerus Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Cerus Corporation maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Cerus Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Cerus Corporation as of December 31, 2005, and 2004, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005 of Cerus Corporation and our report dated February 22, 2006 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP
Palo Alto, California
February 22, 2006

REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Cerus Corporation

We have audited the accompanying balance sheets of Cerus Corporation as of December 31, 2005, and 2004, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2005. 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 the standards of the Public Company Accounting Oversight Board (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, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005 in conformity with U. S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 22, 2006

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CERUS CORPORATION

BALANCE SHEETS
(in thousands, except per share amounts)

	2005	2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,780	$ 39,169
Short-term investments	40,025	56,165
Accounts receivable and other current assets	5,200	4,537
Total current assets	51,005	99,871
Furniture and equipment at cost:		
Laboratory and office equipment	6,306	5,768
Leasehold improvements	7,453	7,173
	13,759	12,941
Less accumulated depreciation and amortization	12,524	11,994
Net furniture and equipment	1,235	947
Long-term investments	6,175	1,175
Other assets	245	85
Total assets	$ 58,660	$ 102,078
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,092	$ 1,476
Current loan and interest payable	4,826	34,500
Accrued compensation and related expenses	2,676	2,749
Accrued contract and other expenses	2,521	2,058
Deferred revenue	11,135	13,217
Deferred gain on loan settlement	—	22,089
Current portion of capital lease obligations	67	—
Total current liabilities	23,317	76,089
Long term portion of capital lease obligations	68	—
Long term debt payable to a related party	—	4,500
Total liabilities	23,385	80,589
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value: issuable in series; 3 shares issued and outstanding at December 31, 2005, and 2004; aggregate liquidation preference of $9,496 at December 31, 2005, and 2004	9,496	9,496
Common stock, $0.001 par value; 50,000 shares authorized: 22,458 and 22,211 shares issued and outstanding at December 31, 2005, and 2004, respectively	23	22
Additional paid-in capital	332,694	332,002
Accumulated other comprehensive loss	(295)	(324)
Accumulated deficit	(306,643)	(319,707)
Total stockholders' equity	35,275	21,489
Total liabilities and stockholders' equity	$ 58,660	$ 102,078

See accompanying notes.

CERUS CORPORATION

STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	2005	2004	2003
Revenue:			
Milestone and development funding	$11,697	$ 4,187	$ 1,022
Government grants and cooperative agreements	12,189	9,724	8,591
Product sales	485	—	52
Total revenue	24,371	13,911	9,665
Operating expenses:			
Research and development	24,134	27,651	52,484
General and administrative	9,578	10,225	11,016
Restructuring	—	2,861	—
Total operating expenses	33,712	40,737	63,500
Loss from operations	(9,341)	(26,826)	(53,835)
Interest and other income (expense):			
Interest income (expense) and other, net	316	(4,327)	(4,432)
Gain on loan settlement	22,089	—	—
Net interest and other income (expense)	22,405	(4,327)	(4,432)
Net income (loss)	$13,064	$(31,153)	$(58,267)
Net income (loss) per common share:			
Basic	$ 0.58	$ (1.41)	$ (3.01)
Diluted	$ 0.55	$ (1.41)	$ (3.01)
Weighted average common shares outstanding used for basic and diluted net income (loss) per share:			
Basic	22,350	22,143	19,367
Diluted	23,950	22,143	19,367

See accompanying notes.

CERUS CORPORATION

STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balances at December 31, 2002	3	$9,496	15,950	$ 16	$276,944	$ —		$ (230,287)	$ 56,169
Issuance of common stock, net of expenses of $236	—	—	6,000	6	54,058	—		—	54,064
Issuance of common stock under stock option and employee stock purchase plans	—	—	111	—	562	—		—	562
Net loss	—	—	—	—	—	—	$ (58,267)	(58,267)	(58,267)
Balances at December 31, 2003	3	9,496	22,060	22	331,564	—		(288,554)	52,528
Issuance of common stock under stock option and employee stock purchase plans	—	—	150	—	438			—	438
Net change in unrealized loss on investments	—	—	—	—	—	(324)	$ (324)	—	(324)
Net loss	—	—	—	—	—	—	(31,153)	(31,153)	(31,153)
Total comprehensive income (loss)							$ (31,477)		
Balances at December 31, 2004	3	9,496	22,211	22	332,002	(324)		(319,707)	21,489
Issuance of common stock under stock option restricted stock, and employee stock purchase plans	—	—	247	1	692	—		—	693
Net change in unrealized gain (loss) on investments	—	—	—	—	—	29	$ 29	—	29
Net income	—	—	—	—	—	—	13,064	13,064	13,064
Total comprehensive income							$ 13,093		
Balances at December 31, 2005	3	$9,496	22,458	$ 23	$332,694	$ (295)		$ (306,643)	$ 35,275

See accompanying notes.

CERUS CORPORATION

STATEMENTS OF CASH FLOWS
(in thousands)

	2005	2004	2003
Operating activities			
Net income (loss)	$ 13,064	$(31,153)	$ (58,267)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	652	2,152	3,291
Gain on settlement of loan	(22,089)	—	—
Stock-based compensation to employees	206	193	—
Stock-based compensation to consultants	—	19	—
Gain on sale of equipment	—	48	(10)
Loss on long-term investment	—	62	—
Changes in operating assets and liabilities:			
Accounts receivable and other current assets	(664)	1,207	(2,877)
Other assets	(160)	71	(4)
Accounts payable	616	(3,167)	(5,917)
Accrued interest payable	326	5,986	5,897
Accrued compensation and related expenses	(74)	674	(401)
Accrued contract research expenses	(302)	(613)	(354)
Other accrued expenses	560	(849)	131
Deferred revenue	(7,082)	12,642	(104)
Net cash used in operating activities	(14,947)	(12,728)	(58,615)
Investing activities			
Purchases of furniture and equipment	(856)	(594)	(297)
Proceeds from sale of equipment	51	—	10
Investments in BioOne Corporation	—	(1,237)	—
Purchases of short-term investments	(5,000)	(76,835)	(191,695)
Sale of short-term investments	8,000	95,725	83,089
Maturities of short-term investments	13,169	11,466	63,644
Net cash provided by (used in) investing activities	15,364	28,525	(45,249)
Financing activities			
Net proceeds from issuance of common stock	693	226	54,626
Loan proceeds (repayments)	(34,500)	—	50,000
Payments on capital lease obligations	—	(19)	(32)
Net cash provided by financing activities	(33,807)	207	104,594
Net increase (decrease) in cash and cash equivalents	(33,389)	16,004	730
Cash and cash equivalents, beginning of period	39,169	23,165	22,435
Cash and cash equivalents, end of period	$ 5,780	$ 39,169	$ 23,165

See accompanying notes.

CERUS CORPORATION

NOTES TO FINANCIAL STATEMENTS

December 31, 2005

1. The Company and Its Significant Accounting Policies

Basis of Presentation

Cerus Corporation (the "Company"), incorporated on September 19, 1991, is developing novel products for cancer, infectious disease and blood safety. The Company is developing cancer immunotherapies based on its *Listeria* vaccine platform, often combined with disease antigens. The Company also is developing the INTERCEPT Blood System, which is designed to enhance the safety of blood components through pathogen inactivation. The Company has collaboration agreements with MedImmune, Inc. ("MedImmune") and The Johns Hopkins University for cancer immunotherapy, and Baxter Healthcare Corporation ("Baxter," a subsidiary of Baxter International Inc.) and BioOne Corporation ("BioOne") for the INTERCEPT Blood System. Effective February 1, 2006, the Company entered into a restructured agreement with Baxter as more fully discussed in Note 11. The Company has received only minimal revenue from product sales of the INTERCEPT platelet system in Europe. Substantially all revenue recognized by the Company to date has resulted from the Company's collaboration agreements with MedImmune, Baxter, BioOne 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 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, preclinical safety studies, external laboratory studies and development activities performed by Baxter. 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

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 and Emerging Issues Task Force ("EITF") 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables," as applicable.

The Company's main sources of revenues through December 31, 2005 have come from its research and development activities and agreements. Development funding for the Company consists 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 MedImmune and the National Marrow Donor Program (the "NMDP") 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. The Company evaluates licenses and research and research and development agreements that contain multiple elements in accordance with EITF 00-21 and accordingly allocates revenue to each element of the agreement based on their relative fair values.

The Company received milestone and up-front consideration totaling $0.5 million and $7.0 million from MedImmune and BioOne, respectively, in the year ending December 31, 2005. The Company received up-front consideration of $1.0 million and $13.0 million from MedImmune and BioOne, respectively, in 2004. Upfront consideration in 2005 and 2004 was deferred and is being recognized ratably over the periods to which the payments relate. There were no other milestone or up-front payments recognized during the years ended December 31, 2005, 2004 and 2003.

The Company receives certain United States government grants that support the Company's efforts 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 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, preclinical safety studies, other laboratory studies, process development and product 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 recorded and revenue recorded from development funding and government grants and collaborative agreements. Actual results may differ from those estimates under different assumptions or conditions.

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. Available-for-sale securities are carried at estimated fair value based on quoted market prices. The Company reports the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income. The Company's available-for-sale securities consist primarily of U.S. government agency securities and corporate debt securities. The available-for-sale securities recorded at amounts that approximate fair value at December 31, 2005, and 2004, totaled $45.1 million and $91.6 million, respectively.

Unrealized gains and losses at December 31, 2005, and 2004 are reported in accumulated other comprehensive income. The Company reviews all of its marketable securities on a regular basis to evaluate

whether any security has experienced an other-than-temporary decline in fair value. As of December 31, 2005, there were no other-than-temporary declines in fair value. 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 two major financial institutions. The Company monitors the financial credit worthiness of the issuers of its investments. All of the Company's investments carry high credit quality ratings, in accordance with its investment policy.

As of December 31, 2005, the Company also maintained a certificate of deposit for approximately $0.2 million with a domestic bank. The Company holds this certificate of deposit for any potential decommissioning resulting from the Company's possession of radioactive material. The certificate of deposit is held to satisfy the financial surety requirements of the California Department of Health Services and is recorded as Other long-term assets on its balance sheet at December 31, 2005.

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").

CERUS CORPORATION

NOTES TO FINANCIAL STATEMENTS—(Continued)

December 31, 2005

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

	2005	2004	2003
Net income (loss):			
As reported	$13,064	$(31,153)	$(58,267)
Add:			
Stock-based compensation expense included in reported net income (loss), net of related tax effects	206	292	—
Less:			
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	2,462	2,404	8,300
Pro forma net income (loss)	$10,808	$(33,265)	$(66,567)
Net income (loss) per share—basic and diluted, as reported			
Basic	$ 0.58	$ (1.41)	$ (3.01)
Diluted	$ 0.55	$ (1.41)	$ (3.01)
Net income (loss) per share—basic and diluted, pro forma			
Basic	$ 0.48	$ (1.50)	$ (3.44)
Diluted	$ 0.45	$ (1.50)	$ (3.44)

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 Income (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, restricted stock units and convertible preferred stock.

CERUS CORPORATION

NOTES TO FINANCIAL STATEMENTS—(Continued)

December 31, 2005

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net income per common share (in thousands, except per share amounts):

	2005	2004	2003
Numerator:			
Net income (loss)	$13,064	$(31,153)	$(58,267)
Denominator:			
Basic weighted average number of common shares outstanding	22,350	22,143	19,367
Effect of dilutive potential common shares resulting from stock options, unvested restricted common stock and ESPP shares	1,600	—	—
Diluted weighted average number of common shares outstanding	23,950	22,143	19,367
Basic net income (loss) per common share	$ 0.58	$ (1.41)	$ (3.01)
Diluted net income (loss) per common share	$ 0.55	$ (1.41)	$ (3.01)

The table below presents stock options, preferred stock and restricted stock units that are excluded from the diluted net income (loss) per common share due to their anti-dilutive effect. (shares in thousands):

	2005	2004	2003
Antidilutive securities—weighted average shares	1,713	4,627	3,887

Comprehensive Income (Loss)

Statement of Financial Accounting Standards No. 130, “Reporting Comprehensive Income,” requires that all items recognized 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. Other comprehensive income for all periods presented is comprised solely of unrealized holding losses on the Company’s available-for-sale securities. Other comprehensive income is reported as a separate component of stockholders’ equity.

Guarantee and Indemnification Arrangements

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 Financial Accounting Standards Board Interpretation No. 45, “Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others” (“FIN 45”). 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.

Disclosures About Segments of an Enterprise

The Company has two reportable segments: blood safety programs and immunotherapies. The blood safety segment primarily comprises research and development of the INTERCEPT Blood Systems. The

immunotherapies segment primarily comprises research and development of vaccines using our *Listeria* platform. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies. There are no transactions between reportable segments.

Prior to October 8, 2004, the Company had one reportable segment, which was the development of biomedical systems using the Company's proprietary technology for controlling biological replication. On June 30, 2004, the Company announced a restructuring of operations to increase resources for its program to develop therapeutic vaccines against cancer and infectious diseases and reduce expenditures for its blood safety programs and administrative expenses. On October 8, 2004, the Company's board of directors approved a strategic plan, which resulted in the two reportable business segments. Senior management of the Company do not view segment results below operating loss and, therefore, interest income, interest expense and other non-operating expenses are not allocated to reportable segments. Expenses related to the Company's June 2004 restructuring were allocated to the blood safety segment. For the periods presented, revenue from Baxter, BioOne and the Armed Forces are included in blood safety programs, and revenue from MedImmune is included in immunotherapies. As of December 31, 2005, the Company had no operations or assets outside of the United States. Segment information for the years ended December 31, 2005, 2004 and 2003 is presented below (in thousands):

	2005	
	Revenue	Operating Loss
Blood safety programs	$13,497	$ 1,094
Immunotherapies	10,874	8,247
Totals	$24,371	$ 9,341

	2004	
	Revenue	Operating Loss
Blood safety programs	$11,317	$ 16,397
Immunotherapies	2,594	10,429
Totals	$13,911	$ 26,826

	2003	
	Revenue	Operating Loss
Blood safety programs	$8,650	$ 48,002
Immunotherapies	1,015	5,833
Totals	$9,665	$ 53,835

New Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" ("FAS 123R"). FAS 123R addresses the accounting for share-based payment transactions in which a company receives employee services in exchange for either equity instruments of the company or liabilities that are based on the fair value of a company's equity instruments. Under FAS 123R, companies will no longer be able to account for share-based compensation transactions using the intrinsic value method in accordance with APB 25, as described in the "Stock-Based Compensation" section of this Note 1. Instead, companies will be required to account for such transactions using

a fair value method and recognize expense in the statements of operations. FAS 123R is effective for interim or annual periods beginning after December 31, 2005. The Company is required to adopt FAS 123R no later than the beginning of the first quarter of 2006. FAS 123R permits public companies to adopt its requirements using either the modified prospective method or the modified retrospective method. Under the modified prospective method, compensation cost is recognized for all share-based payments granted after the effective date as well as for all share-based payments granted prior to the effective date which remain unvested on the effective date. Under the modified retrospective method, the same provisions would apply but the company could also restate its earnings in certain prior periods based on the stock compensation amounts included in its previous pro forma disclosures. The Company has determined it will use the modified prospective approach in 2006. The effect of adoption of FAS 123R cannot be predicted at this time because it will depend on share-based payments granted in the future. Pro forma disclosures regarding the effect on the Company's net income (loss) and net income (loss) per common share in 2005 and prior years, had the Company applied the fair value method of accounting for share-based compensation as prescribed by FAS 123, are contained in the "Stock-Based Compensation" section of this Note 1.

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 153 ("FAS 153"), "Exchanges of Nonmonetary Assets which amends Accounting Principles Board No. 29 ("APB 29"), "Accounting for Nonmonetary Transactions. FAS 153 eliminates the exception from fair value measurement for nonmonetary exchanges of similar productive assets in AP29 and instead states that a nonmonetary exchange has commercial substance and thus should be recorded at fair value if the future cash flows of the entity are expected to change as a result of a non-monetary exchange. FAS 153 is effective for the Company for nonmonetary asset exchanges occurring in 2006. The Company is currently evaluating the future impact that adopting FAS 153 will have on its financial statements.

In May 2005 the FASB issued Statement of Financial Accounting Standards No. 154 ("FAS 154"), "Accounting Changes and Error Corrections," which replaces Accounting Principles Board No. 20 ("APB 20"), "Accounting Changes," and Statement of Financial Accounting Standards No. 3, "Reporting Accounting Changes in Interim Financial Statements." FAS 154 applies to all voluntary changes in accounting principle, and changes the requirements for accounting for and reporting of a change in accounting principle. FAS 154 requires retroactive application to prior periods' financial statements of a voluntary change in accounting principle unless it is impracticable to do so. APB 20 previously required that most voluntary changes in accounting principle be recognized with a cumulative effect adjustment in net income of the period of the change. FAS 154 is effective for accounting changes made in annual periods beginning after December 15, 2005. The Company is currently evaluating the future impact that adopting FAS 154 will have on its financial statements.

2. Development and License Agreements

Agreement with MedImmune

In April 2004, the Company entered into an agreement with MedImmune to co-develop a therapeutic vaccine designed to target antigens expressed in breast, prostate and colon cancer, as well as metastatic melanoma. A vaccine is being developed using the Company's Listeria vaccine platform and MedImmune's EphA2 cancer antigen. Under the terms of the agreement, MedImmune is responsible for clinical testing, manufacturing and commercialization of any product resulting from this collaboration. The Company is responsible for preclinical development of a therapeutic vaccine candidate. The Company is receiving development funding and contingent milestone payments and will receive royalties on future product sales. Upon achievement of a preclinical milestone, the Company has the option to require MedImmune to purchase $5.0 million of its common stock at a per share price of 115% of the average closing price of the Company's stock for

30 days prior to achievement of the milestone. In May 2004, the Company received an up-front payment of $1.0 million from MedImmune. The up-front payment is being deferred and recognized ratably as development funding over the preclinical development period, estimated to be 24 months. In September 2005 the Company received a $0.5 million milestone payment from MedImmune upon a lead candidate strain being selected for further preclinical development, which was recognized in the period ending September 30, 2005. The Company recognized $2.4 million and $1.6 million of revenue under this agreement in the years ended December 31, 2005, and 2004, respectively.

Restructured Agreements with Baxter

Prior to February 2005, Baxter and the Company shared development expenses for the INTERCEPT Blood Systems for platelets (the "platelet system") and red blood cells (the "red blood cell system") under the parties' existing development and commercialization agreements. The agreements provided for the Company to be solely responsible for funding development expenses for the INTERCEPT Blood System for plasma (the "plasma system"). During the years ended December 31, 2005, 2004 and 2003, the Company recognized development funding of $1.6 million, $0.8 million and $0.4 million, respectively, under these agreements. Under the agreements, Baxter has been responsible for manufacturing and marketing the platelet system, which is approved for sale in some countries in Europe. The agreements provided for the Company to receive approximately 33.5% of revenue from sales of system disposables after each party is reimbursed for its cost of goods to the extent cost exceeds specific amounts. The Company recognized product sales of $0.5 million in the year ended December 31, 2005. Recognition of product sales revenue was deferred from the fourth quarter of 2003 through December 31, 2004, as a result of revenue sharing payments being withheld by Baxter due to a dispute over the timing of repayment of a loan from Baxter Capital Corporation ("Baxter Capital") (see Note 4).

In February 2005, Baxter and the Company entered into agreements that reaffirmed the previous agreements in certain respects and modified them in other respects (the "2005 agreements"). Under the 2005 agreements, Baxter remained solely responsible for sales and marketing expenses for the products/countries as to which it maintained commercialization rights. For 2005 and 2006, Baxter agreed to fund $13.1 million of expenses for platelet and plasma system sales and marketing and for activities directed toward CE mark approval of the plasma system. Baxter also agreed to furnish specified levels of personnel to conduct sales and marketing of the platelet system and, upon approval, plasma system in Europe. The Company's agreements with Baxter provided for sales and marketing strategy surrounding Baxter's commercialization rights to be set by a joint Cerus/Baxter governance committee.

Our arrangement with Baxter to equally fund development work for the platelet system and the red blood cell system also was terminated by the 2005 agreements. Commencing January 1, 2005, each company agreed to bear its own expenses regarding ongoing discussions with the FDA to gain clarity on the remaining steps in the U.S. regulatory process for the platelet system.

Under the 2005 agreements, the Company remained responsible for funding 100% of development expenses for the plasma system, except that $2.2 million of Baxter's $13.1 million commitment (described above) may be applied to activities directed toward obtaining CE mark approval of and launch preparation for the plasma system. Baxter agreed to cooperate with the Company to complete certain activities required for the CE mark application. Such activities shall, except for the right to apply such $2.2 million, be at the Company's expense. For the year ended December 31, 2005, the Company applied $1.2 million of Baxter's commitment to expenses incurred during the period directed toward obtaining CE mark approval of the plasma system, which was recognized as development funding revenue.

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NOTES TO FINANCIAL STATEMENTS—(Continued)

December 31, 2005

Under a separate agreement in February 2005 with Baxter Capital relating to the $50.0 million loan and accrued interest, the Company paid $34.5 million to Baxter Capital in February 2005 and entered into a promissory note for $4.5 million, payable with 8% interest in December 2006. Baxter Capital agreed to accept these payments in full satisfaction of the loan obligation, and Baxter Capital and the Company dismissed the related legal actions. As a result of the loan settlement, the Company received a payment of $0.2 million from Baxter representing withheld revenue share from product sales through December 31, 2004. This amount was recognized as product sales revenue during the three months ended March 31, 2005, in addition to revenue related to product sales during the period.

Baxter has agreed to manufacture systems and components, on a cost-plus basis, through 2008. Since the agreements do not require Baxter to manufacture in an FDA-approved facility, the Company will need to undertake additional validation steps before use of such items in the United States. Baxter has agreed to supply only very limited types of components for the prototype red blood cell system.

Effective February 1, 2006, the Company entered into a restructured agreement with Baxter as more fully discussed in Note 11.

Agreements with BioOne

In April 2004, the Company made an investment in the common stock of BioOne, a privately held Japanese corporation. BioOne was formed in 2004 to develop technologies to improve the safety of blood products in Asia, and is funded by equity investments from Japanese venture capital firms, other corporations and individual investors. Because the Company's initial investment represented greater than 20% of BioOne's voting equity securities, the Company accounted for this investment under the equity method for the three months ended June 30, 2004. During this period, the Company reported its share of BioOne's net losses for that period as a loss from equity affiliate and as a reduction of its investment.

In June 2004, Baxter and the Company entered into an agreement with BioOne for commercialization of the INTERCEPT Blood System for platelets in parts of Asia. Under the terms of the agreement, BioOne is responsible, at its expense, for seeking regulatory approvals and will have exclusive rights to market and distribute the INTERCEPT Blood System for platelets in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore, following their receipt of regulatory approval in each of those countries. In July 2004 and October 2004, Baxter and the Company each received up-front payments of $10.0 million from BioOne. The Company's portion of the up-front payments is being deferred and recognized ratably as development funding over the development period. The agreement also provides for contingent milestone payments and royalties on future product sales, which would be shared equally by Baxter and the Company. The Company recognized $5.5 million and $1.7 million of revenue under this agreement during the years ended December 31, 2005, and 2004, respectively.

In December 2004, Baxter and the Company signed a letter of intent with BioOne to enter into a definitive agreement for commercialization of the INTERCEPT Blood System for plasma in parts of Asia. Under the letter of intent, the Company received a payment of $3.0 million from BioOne, which was recorded as deferred revenue as of December 31, 2004. A definitive agreement with BioOne for the plasma system was signed by Baxter and the Company in June 2005, and in December 2005 the Company received additional up-front payments of $2.0 million in cash and $5.0 million in BioOne's equity, both of which were recorded upon receipt as deferred revenue to be amortized over the remaining development period. The Company recognized $1.8 million of revenue under this agreement during the year ended December 31, 2005.

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NOTES TO FINANCIAL STATEMENTS—(Continued)

December 31, 2005

The Company made an additional $1.1 million investment in BioOne equity securities in July 2004. As a result of dilution from additional concurrent third party investments in BioOne, the Company then held less than 20% of the outstanding voting securities of BioOne and began accounting for its investment in BioOne under the cost method. As partial payment for rights to the plasma system in BioOne's territories, in December 2005 the Company received shares and a warrant, exercisable at a nominal price, for additional shares valued at $5.0 million based on a concurrent financing with new and existing investors completed by BioOne. The Company continues to hold less than a 20% interest in the voting securities of BioOne and thus continues to account for its investment under the cost method. As of December 31, 2005, the Company's investment in BioOne is $6.2 million and is included in long-term investments on its balance sheets. The Company has determined that there is no impairment of this investment as of December 31, 2005.

Cooperative Agreements with the U.S. Armed Forces

In February 2001, the Company was awarded $2.6 million under a cooperative agreement with the Army Medical Research Acquisition Activity division of the Department of Defense. In September 2002 and May 2003, January 2004 and July 2004, the Company was awarded additional funding of $5.0 million, $6.0 million $5.5 million and $3.7 million, respectively, all 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 U.S. armed forces for medical transfusions. Under the conditions of the agreements, the Company is conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites that are of concern to the U.S. armed forces. This funding also supports advanced development of the Company's blood safety technologies. The Company recognized $4.1 million, $8.9 million and $8.2 million of revenue under these agreements during the years ended December 31, 2005, 2004 and 2003, respectively.

In October 2004, the Company received a $6.5 million award from the Army Medical Research Acquisition Activity division of the Department of Defense for the research and development of vaccines for biodefense and cancer. The award funds work to be performed through November 2006. The Company received an advance payment of $0.8 million under this award, which was recorded as deferred revenue as of December 31, 2004. The Company recognized $6.5 million of revenue from this award in the year ended December 31, 2005.

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 provided 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 agreement expired on March 31, 2004. The Company recognized $0.04 million and $0.5 million in development funding from the NMDP during the years ended December 31, 2004, and 2003, respectively. No revenue was recognized in the year ended December 31, 2005.

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NOTES TO FINANCIAL STATEMENTS—(Continued)

December 31, 2005

3. Investments

Available-for-sale securities comprised the following at December 31 (in thousands):

	2005			
	Adjusted Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
U.S. government investments:				
Original maturities less than one year	$ —	$ —	$ —	$ —
Original maturities one year or greater	39,307	—	(289)	39,018
Total government investments	39,307	—	(289)	39,018
Corporate debt investments:				
Original maturities less than one year	$ —	$ —	$ —	$ —
Original maturities one year or greater	1,013	—	(6)	1,007
Total corporate investments	1,013	—	(6)	1,007
Total short-term investments	$ 40,320	$ —	$ (295)	$ 40,025

	2004			
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. government investments:				
Original maturities less than one year	$ 1,024	$ —	$ (19)	$ 1,005
Original maturities one year or greater	44,682	1	(293)	44,390
Total government investments	45,706	1	(312)	45,395
Corporate debt investments:				
Original maturities less than one year	1,714	—	(5)	1,709
Original maturities one year or greater	9,069	2	(10)	9,061
Total corporate investments	10,783	2	(15)	10,770
Total short-term investments	$ 56,489	$ 3	$ (327)	$ 56,165

All of the Company's available-for-sale securities have been in an unrealized loss position for more than 12 months. The Company has the ability and intent to hold these investments to maturity and as a result, does not anticipate recognizing these losses.

4. Loan Payable to Baxter Capital Corporation

In January 2003, the Company received proceeds from a $50.0 million loan from Baxter Capital, a financial subsidiary of Baxter International Inc. separate from Baxter. The interest rate on the loan was 12% per annum. Under the terms of the loan, no payment of principal or interest was due until 2008. The loan was secured by the Company's current 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 alleged that changes in the Company's business constituted a default under the loan agreement. The Company did not agree that any default occurred and therefore believed that, under the terms of the loan, no principal or interest payments should be due until January

2008. Due to uncertainty as to the potential outcome of the legal proceedings, the Company classified amounts due to Baxter Capital under the loan as a current liability on its balance sheet at December 31, 2003.

Concurrent with the 2005 restructured agreements between Baxter and the Company, Baxter Capital and the Company entered into an agreement under which the Company immediately paid $34.5 million to Baxter Capital and entered into a promissory note for $4.5 million, payable with 8% interest in December 2006. Baxter Capital agreed to accept these payments in full satisfaction of the loan obligation, and the parties dismissed all related legal actions.

Because the settlement of litigation and the restructured agreements with Baxter and Baxter Capital related to conditions that required estimates and existed as of the date of the balance sheet at year-end in 2004, the Company adjusted the balance sheet as of December 31, 2004, to reflect the terms of the February 2005 loan settlement agreement. The December 31, 2004, balance sheet included a current payable of $34.5 million, which was paid in February 2005 to Baxter Capital, a $0.8 million accrual included within other accrued expenses for other estimated expenses in connection with the restructured commercialization agreements with Baxter, a deferred gain of $22.1 million on the loan settlement, which was recognized as a non-operating gain in the first quarter of 2005, and long-term debt of $4.5 million, representing the note due to Baxter Capital in December 2006, which accrues interest at 8%. As of December 31, 2005, the $4.5 million note payable and the related accrued interest of $0.3 million are included in current loan and interest payable on the Company's balance sheet.

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 $0.1 million, $0 and $0.1 million, respectively, for the years ended December 31, 2005, 2004 and 2003, respectively.

Future minimum payments under operating leases are as follows (in thousands):

Year ending December 31,	Operating Leases
2006	$ 1,123
2007	644
2008	467
2009	304
2010	11
Total minimum lease payments	$ 2,549

Rent expense for office facilities was $1.1 million, $1.2 million and $1.3 million for the years ended December 31, 2005, 2004 and 2003, 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

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NOTES TO FINANCIAL STATEMENTS—(Continued)

December 31, 2005

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 allegedly false and misleading statements regarding the compound used in the Company's red blood cell system. 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. On May 24, 2004, the plaintiffs filed a consolidated complaint. The consolidated complaint abandons the allegations raised in the original complaints. Instead, the plaintiffs claim that the defendants issued false and misleading predictions regarding the initiation and completion of clinical trials, submission of regulatory filings, receipt of regulatory approval and other milestones in the development of the INTERCEPT Blood Systems for platelets, plasma and red blood cells. The consolidated complaint retains the same class period alleged in the original complaints. On June 17, 2004, the plaintiffs filed an amended consolidated complaint substantially similar to the previous consolidated complaint with additional allegations attributed to a confidential witness. On July 20, 2004, the defendants moved to dismiss the amended consolidated complaint. On January 20, 2005, the Court dismissed the complaint with leave to amend within 60 days. The Company believes that this matter will not have a material effect on its results of operations or financial position; however, it cannot predict the outcome of this litigation.

In addition, certain of the Company's present and former directors and officers have been named as defendants in two virtually identical derivative lawsuits in the Superior Court for the County of Contra Costa, which name the Company as a nominal defendant. The plaintiffs in these actions are certain stockholders who seek to bring derivative claims on behalf of the Company against the defendants. The complaints allege breach of fiduciary duty and related claims. To date, there have been no further substantial developments in this lawsuit. The Company believes that this matter will not have a material effect on its results of operations or financial position; however, it cannot predict the outcome of this litigation.

6. Stockholders' Equity

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 shares of the Company's common stock. If all shares of Series B preferred stock were converted to common stock, 332,700 shares of common stock would be issued, which represents approximately 1.5% of the outstanding common shares of the Company at December 31, 2005. The Company has the right to redeem the Series B preferred stock prior to conversion for a payment of $9.5 million.

Stockholder Rights Plan

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 acquirer, 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.

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 5,680,000 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.

Employee Stock Purchase Plan

The Company has reserved 820,500 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 66,908, 90,757 and 86,300 shares under the Purchase Plan during the years ended December 31, 2005, 2004 and 2003, respectively. At December 31, 2005, 451,853 shares were available for issuance. The weighted average fair value per share of the rights granted during the years ended December 31, 2005, 2004 and 2003 using the Black-Scholes model was $1.330, $2.286 and $3.004, respectively.

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.

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December 31, 2005

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		
	2005	2004	2003	2005	2004	2003
Expected volatility	.599	.602	.884	.590	.612	.885
Risk-free interest rate	4.32%	3.37%	2.96%	4.36%	1.63%	2.24%
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 (in thousands except per share amounts):

	Number of Options Outstanding	Weighted Average Exercise Price per Share ($)
Balances at December 31, 2002	3,159	34.703
Granted	1,026	5.944
Cancelled	(607)	32.353
Exercised	(24)	2.682
Balances at December 31, 2003	3,554	27.029
Granted	2,078	2.599
Cancelled	(1,332)	28.612
Exercised	(6)	0.544
Balances at December 31, 2004	4,294	14.749
Granted	885	7.487
Cancelled	(457)	2.934
Exercised	(124)	21.253
Balances at December 31, 2005	4,598	13.025

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December 31, 2005

The weighted average fair value of options granted during the years ended December 31, 2005, 2004 and 2003 was $3.369, $1.173 and $3.416 per share, respectively. At December 31, 2005, options to purchase 1.6 million shares of common stock were available for future grant.

(Shares in thousands)

	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
$1.950—2.050	153	8.60	$ 2.048	50	$ 2.049
$2.100—2.280	670	8.50	$ 2.273	168	$ 2.267
$2.360—2.721	514	7.60	$ 2.430	150	$ 2.520
$2.820—2.890	118	8.94	$ 2.880	42	$ 2.861
$2.950—3.250	544	8.37	$ 3.234	230	$ 3.225
$3.430—4.740	514	8.54	$ 4.268	193	$ 4.169
$5.000—8.750	290	7.78	$ 7.226	169	$ 7.206
$8.860—8.860	580	9.75	$ 8.860	24	$ 8.860
$9.010—26.500	468	4.34	$ 19.940	439	$ 20.129
$26.875—75.250	747	5.69	$ 48.075	723	$ 48.077
	4,598	7.63	$ 13.025	2,188	$ 21.737

Restricted Stock Units

In March 2004, the Company granted a total of 111,884 restricted stock units to current employees. Subject to each grantee's continued employment, shares underlying restricted stock unit grants vest in four semi-annual installments. The Company has issued 56,232 shares for restricted stock units that vested in 2005. In accordance with APB 25, the Company recorded compensation expense based on the fair value of the underlying common stock as of the grant date, recognized over the vesting period. All restricted stock units granted in 2004 were valued at $3.38 per share. The Company recorded compensation expense of $0.2 million related to restricted stock units in the year ended December 31, 2005. As of December 31, 2005, 26,324 restricted stock units were outstanding under the March 2004 grant.

7. Restructuring

On June 30, 2004, the Company announced a restructuring of operations to increase resources for its program to develop therapeutic vaccines against cancer and infectious diseases and reduce expenditures for its blood safety programs and administrative expenses. As a result of the restructuring, the Company reduced its workforce by approximately 35% and reduced other operating expenses. During the year ended December 31, 2004, the Company recorded aggregate charges of $2.9 million associated with this restructuring on its statement of operations. The $2.9 million of restructuring charges primarily included severance benefits to employees. As of December 31, 2004, the Company reported accrued restructuring of $0.5 million on its balance sheets. The Company did not record restructuring charges during the year ended December 31, 2005 and all activity affecting the accrued restructuring balance was the result of cash payments. As of December 31, 2005, the accrual for restructuring was $0.2 million, related to severance benefits payable in installments until May 2006. The Company does not expect to record further costs related to this restructuring.

CERUS CORPORATION

NOTES TO FINANCIAL STATEMENTS—(Continued)

December 31, 2005

8. 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 (in thousands):

	December 31,	
	2005	2004
Net operating loss carryforward	$ 79,200	$ 103,400
Research and development credit carryforward	23,800	23,300
Deferred revenue	—	5,400
Capitalized research and development	30,600	5,200
Certain expenses not currently deductible for tax purposes	2,500	2,900
Accrued liabilities	700	800
Other	3,100	2,700
Gross deferred tax assets	139,900	143,700
Valuation allowance	(139,900)	(143,700)
Net deferred tax assets	$ —	$ —

The valuation allowance decreased by $3.8 million and increased by $11.4 million and $29.2 million for the years ended December 31, 2005, 2004, and 2003, respectively. 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.

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 adjusted 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. For the year ending December 31, 2005, the Company reported net income of $13.1 million on its statement of operations however was in a loss position for both federal and state taxes. The difference between net income and tax loss are due to temporary differences between US GAAP and the respective tax laws.

At December 31, 2005, the Company had net operating loss carryforwards of approximately $201.1 million for federal and $181.0 million for state income tax purposes. The Company also had research and development tax credit carryforwards of approximately $16.3 million for federal income tax purposes and approximately $11.5 million for state income tax purposes at December 31, 2005. The federal net operating loss and tax credit carryforwards expire between the years 2007 and 2025. The state net operating loss carryforwards expire between the years 2006 and 2014. 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.

CERUS CORPORATION

NOTES TO FINANCIAL STATEMENTS—(Continued)

December 31, 2005

9. 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, 2005, 2004 and 2003. 10. Quarterly Financial Information (Unaudited and in thousands except per share amounts)

	Three Months Ended			
	March 31, 2005	June 30, 2005	September 30, 2005	December 31, 2005
Revenue:				
Milestone and development funding	$ 2,933	$ 2,594	$ 3,292	$ 2,878
Government grants and cooperative agreements	3,228	2,800	3,519	2,642
Product sales	240	86	69	90
Total revenue	6,401	5,480	6,880	5,610
Operating expenses:				
Research and development	5,049	5,881	6,626	6,578
General and administrative	2,421	2,616	2,161	2,380
Total operating expenses	7,470	8,497	8,787	8,958
Loss from operations	(1,069)	(3,017)	(1,907)	(3,348)
Gain on loan settlement	22,089	—	—	—
Net interest income (expense)	365	256	241	(546)
Net income (loss)	$21,385	$(2,761)	$ (1,666)	$ (3,894)
Net income (loss) per share—basic	$ 0.96	$ (0.12)	$ (0.07)	$ (0.17)
Net income (loss) per share—diluted	$ 0.92	$ (0.12)	$ (0.07)	$ (0.17)

	Three Months Ended			
	March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004
Revenue:				
Milestone and development funding	$ 281	$ 465	$ 1,215	$ 2,226
Government grants and cooperative agreements	3,366	3,301	2,324	733
Total revenue	3,647	3,766	3,539	2,959
Operating expenses:				
Research and development	8,668	8,720	5,190	5,073
General and administrative	3,043	2,919	1,989	2,274
Restructuring	—	2,465	396	—
Total operating expenses	11,711	14,104	7,575	7,347
Loss from operations	(8,064)	(10,338)	(4,036)	(4,388)
Net interest and other expense	(1,130)	(1,209)	(1,024)	(964)
Net loss	$ (9,194)	$(11,547)	$ (5,060)	$ (5,352)
Net loss per share—basic and diluted	$ (0.42)	$ (0.52)	$ (0.23)	$ (0.24)

CERUS CORPORATION

NOTES TO FINANCIAL STATEMENTS—(Continued)

December 31, 2005

11. Subsequent Event – Baxter Renegotiation

Effective February 1, 2006, the Company entered into a restructuring of its agreements with Baxter related to the INTERCEPT Blood System. Under terms of the 2006 agreement, the Company gained worldwide rights to the INTERCEPT platelet and plasma systems previously held by Baxter, excluding certain Asian countries covered in agreements with BioOne. The Company will pay Baxter royalties on future product sales, replacing terms of the previous agreement, in which the Company received a defined share of gross profit from product sales. The royalty rates vary by product, with a rate of 10% of net sales for the platelet system, 3% for the plasma system and 5% for the red blood cell system. Baxter has agreed to supply certain transition services, including regulatory, technical and back-office support, in 2006 at the Company's expense and to conduct certain continued development efforts relating to the plasma system at Baxter's expense. The Company will record gains and deferred gains of approximately $6.5 million in the period ending March 31, 2006, resulting largely from the disbursement to the Company of funds that remain from a $13.1 million escrow account established in the 2005 agreement to fund commercialization of the platelet and plasma systems in Europe. The majority of the disbursed funds must be spent on certain specified European activities associated with the commercialization of the platelet and plasma systems, and any such funds that remain unspent by the end of 2006 will be split evenly between the Company and Baxter. As part of the agreement, the Company purchased UVA illumination devices and may purchase other finished goods and work in process from Baxter's inventory for use with the platelet and plasma systems. The Company also repaid the $4.5 million promissory note plus accrued interest owed to Baxter Capital that was originally due in December 2006.

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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 24th day of February 2006.

CERUS CORPORATION

By: /s/ Claes Glassell
Claes Glassell
President and Chief Executive Officer

Each person whose signature appears below constitutes and appoints Claes Glassell and William J. Dawson, 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/ Claes Glassell **Claes Glassell**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 24, 2006
/s/ William J. Dawson **William J. Dawson**	Chief Financial Officer and Vice President, Finance *(Principal Financial and Accounting Officer)*	February 24, 2006
/s/ B. J. Cassin **B. J. Cassin**	Chairman of the Board	February 24, 2006
/s/ Timothy B. Anderson **Timothy B. Anderson**	Director	February 24, 2006
/s/ Laurence M. Corash **Laurence M. Corash, M.D.**	Director	February 24, 2006
/s/ Bruce C. Cozadd **Bruce C. Cozadd**	Director	February 24, 2006
/s/ William R. Rohn **William R. Rohn**	Director	February 24, 2006

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INDEX TO EXHIBITS

Exhibit Number	Description of Exhibit
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
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.

Exhibit 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Forms 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 in the Registration Statements on Form S-3 (Nos. 333-93481, 333-47224, 333-61460, 333-61910, 333-67286, 333-125043 and 333-127541) of Cerus Corporation and in the related Prospectuses of our report dated February 24, 2006 with respect to the financial statements of Cerus Corporation and of our report dated February 24, 2006 with respect to Cerus Corporation management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting, of Cerus Corporation, included in this Form 10-K.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 22, 2006

Exhibit 31.1

CEO CERTIFICATION

I, Claes Glassell, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    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 an 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 officer(s) 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 the 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: February 24, 2006

/s/ Claes Glassell

Claes Glassell
Chief Executive Officer

Exhibit 31.2

CFO CERTIFICATION

I, William J. Dawson, 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 internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   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 an 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 officer(s) 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 the 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: February 24, 2006

/s/ William J. Dawson

William J. Dawson
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Claes Glassell, the Chief Executive Officer of Cerus Corporation (the "Company") and William J. Dawson, 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, 2005, 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 24th day of February 2006.

/S/ WILLIAM J. DAWSON
William J. Dawson
Chief Financial Officer

/S/ CLAES GLASSELL
Claes Glassell
Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission (the "SEC") or its staff upon request.

This certification "accompanies" the Form 10-K to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K, irrespective of any general incorporation language contained in such filing).