CERUS CORP
Form 10-K/A
May 03, 2005

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

Amendment No. 1

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

For the fiscal year ended December 31, 2004

OR

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

Commission file number 0-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**68-0262011**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)
2411 Stanwell Dr. Concord, California	**94520**
(Address of principal executive offices)	(Zip Code)

(925) 288-6000

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $.001 per share

(Title of Class)

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

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

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

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 $43,164,330.(1)

As of February 28, 2005, there were 22,299,673 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 2005 annual meeting of stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than April 30, 2005, are incorporated by reference into Part III of this annual report on Form 10-K.

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(1) Based on a closing sale price of $2.39 per share on June 30, 2004. Excludes 4,060,277 shares of the registrant s common stock held by executive officers, directors and affiliates at June 30, 2004.

This Amendment No. 1 (this Form 10-K/A) to Cerus Annual Report on Form 10-K for the year ended December 31, 2004 that was originally filed on March 16, 2005 (the Original Filing), is being filed to add certain information required by Part II, Item 9A.

For the convenience of the reader, this Form 10-K/A sets forth the Original Filing in its entirety. However, this Form 10-K/A only amends and restates the following Items of the Original Filing:

- Item 9A. Contols and Procedures.
- Item 15. Exhibits and Financial Statement Schedules.

In addition, this Form 10-K/A includes Management s Report on Internal Control Over Financial Reporting and the related Report of Ernst & Young LLP, Independent Registered Public Accounting Firm, on Internal Control over Financial Reporting at Part IV, Item 15, a Consent of Independent Registered Public Accounting Firm at Exhibit 23.1 and certifications from Cerus Chief Executive Officer and Chief Financial Officer at Exhibits 31.1, 31.2 and 32.1. No attempt has been made in this Form 10-K/A to modify or update other disclosures presented in the Original Filing. This Form 10-K/A does not reflect events occurring after the filing of the Original Filing or modify or update disclosures, including the exhibits to the Original Filing, affected by subsequent events. Accordingly, this Form 10-K/A should be read in conjunction with Cerus filings made with the Securities and Exchange Commission subsequent to the date of the Original Filing.

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PART I

This report contains forward-looking statements. These forward-looking statements are based on our current expectations about our business and industry, and include, but are not limited to, statements concerning potential efficacy of products, our plans or expectations concerning development and commercialization of our current products and product candidates; conduct of clinical trials of our product candidates; regulatory submissions and approvals; our ability to address certain markets; manufacturing and supply for our clinical trial and commercial requirements; reliance on third parties for marketing, sales and distribution capabilities; evaluation of additional product candidates for subsequent clinical and commercial development; and potential outcomes of litigation. In some cases, these statements may be identified by terminology such as anticipate, believe, continue, estimate, expect, hope, may, plan, potential predict, should o or the negative of such terms and other comparable terminology. In addition, statements that refer to expectations or other characterizations of future events or circumstances are forward-looking statements. These statements involve known and unknown risks and uncertainties that may cause our or our industry s results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, but are not limited to, those discussed under the captions Business, Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations. Forward-looking statements not specifically described above also may be found in these and other sections of this report. Any forward-looking statements speak only as of the date of this report and we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of this report.

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

Item 1. *Business*

Overview

We are developing novel technologies to provide safer and more effective options to patients in areas with substantial unmet medical needs, particularly within the fields of cancer, infectious disease and blood safety. We are employing our proprietary vaccine platform, often with public domain and proprietary antigens, to develop new therapies for cancer and infectious disease. We have three therapeutic cancer vaccine products in development using our *Listeria* vaccine platform; one in collaboration with MedImmune, Inc., or MedImmune, and two with The Johns Hopkins University. We are also collaborating with subsidiaries of Baxter International Inc., or Baxter, and with BioOne Corporation, or BioOne, on the INTERCEPT Blood System, which is designed to enhance the safety of donated blood components by inactivating viruses, bacteria, other pathogens and white blood cells. The INTERCEPT Blood System is based on our Helinx technology for controlling biological replication. The INTERCEPT Blood System for platelets, or platelet system, is currently being marketed by Baxter in Europe.

On June 30, 2004, we announced the realignment of our operations to increase resources for our programs to develop therapeutic vaccines against cancer and infectious diseases and reduce expenditures for our blood safety programs and administrative expenses. As a result of the realignment, we reduced our workforce by approximately 35% and also reduced our operating expenses.

On February 3, 2005, we announced an agreement to restructure our collaboration with Baxter related to the INTERCEPT Blood System. Under the terms of the agreement, Baxter has agreed to continue to invest in commercialization activities in Europe in 2005 and 2006 for the platelet system and INTERCEPT Blood System for plasma, or plasma system. Baxter also has agreed to work collaboratively with us on the preparation of a CE Mark application for the plasma system. Baxter has an option beyond 2006 to continue as our exclusive European marketing partner for the platelet and plasma systems. Together with Baxter, we will continue to pursue regulatory approval for the platelet system in the United States. We will

also continue to collaborate on commercialization activities for the platelet and plasma systems in regions outside the United States and Canada that are not covered by existing agreements with BioOne. Under the terms of the restructured agreement, we gained worldwide rights for the INTERCEPT Blood System for red blood cells, or red blood cell system, and also U.S. and Canadian rights for the plasma system previously held by Baxter. As a result, we are solely responsible for development and commercialization of the red blood cell system worldwide and the plasma system in the United States and Canada. Baxter continues certain manufacturing responsibilities in support of our development and commercialization activities. Under a separate agreement, we paid $34.5 million to Baxter Capital Corporation on February 3, 2005, and executed a promissory note for $4.5 million, payable with interest in December 2006. Baxter Capital has agreed to accept these payments in full satisfaction of the loan obligation of $50.0 million plus accrued interest that had been outstanding and both parties dismissed the related legal actions.

The restructuring of our collaboration with Baxter does not change the relationship with our Asian partner, BioOne. In June 2004, we announced an agreement under which BioOne would market and distribute the platelet system in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore, following receipt of regulatory approval in each of those countries. In December 2004, we also entered into a letter of intent with BioOne for commercialization of the plasma system in parts of Asia.

It is our objective that our spending in support of research, development and commercialization of the INTERCEPT programs be balanced with development funding for such programs from Baxter, BioOne, the United States Armed Forces and others. We plan to continue technical support of Baxter s commercialization efforts for the platelet system in Europe. Together with Baxter, we also are working with the United States Food and Drug Administration, or FDA, on advancing the regulatory process for the platelet system in the United States. We expect to continue our support of Baxter s submission of an application for CE Mark approval for the plasma system in Europe, which we have prioritized above further regulatory activities on our part in the United States. We will also continue our own research and development activities relating to our red blood cell program with funding from the United States Armed Forces. Finally, we expect to invest in the pre-clinical development of our immunotherapy programs in both cancer and infectious disease at spending levels in excess of funding received from partners and government agencies.

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

Product Development

We are developing immunotherapies to treat cancer and infectious disease and systems to inactivate infectious pathogens and harmful white blood cells in platelets, fresh frozen plasma, or FFP, and red blood cells. We have incurred total research and development expenses of $27.7 million, $52.5 million and $56.4 million for the years ended December 31, 2004, 2003 and 2002, respectively. The following table identifies our product development programs:

Program	Therapeutic Indication	Cerus Product in Development	Development Status	Collaborator
Immunotherapy	Colorectal cancer metastasized to liver	Attenuated *Listeria*	Pre-clinical development of product candidate; IND submission planned for late 2005	The Johns Hopkins University
Immunotherapy	Pancreatic and ovarian cancer	Attenuated *Listeria* with Mesothelin	Pre-clinical development of product candidate	The Johns Hopkins University
Immunotherapy	Breast, prostate and colon cancers and metastatic melanoma	Attenuated *Listeria* with EphA2	Pre-clinical development of product candidate	MedImmune
Immunotherapy	Anthrax vaccine	KBMA platform	Pre-clinical research and development	National Institutes of Health
Blood Safety Platelets	Surgery, cancer chemotherapy, transplantation, bleeding disorders	INTERCEPT Blood System for platelets	CE mark received and product is being marketed in certain countries in Europe; U.S. Phase III clinical trial completed, additional independent data analysis to be submitted to FDA, supplemental clinical trial may be required	Baxter in U.S., Europe and other countries; BioOne in Asia
Blood Safety Plasma (FFP)	Surgery, transplantation, bleeding disorders	INTERCEPT Blood System for plasma	Phase III clinical trials completed; submission of CE Mark application planned for late 2005	Baxter in Europe; letter of intent with BioOne in Asia
Blood Safety Red Blood Cells	Surgery, transplantation, anemia, cancer chemotherapy, trauma	INTERCEPT Blood System for red blood cells	Phase III clinical trials were terminated in September 2003 due to the detection of antibodies in two patients; R&D on potential modifications to the system is ongoing	

Immunotherapy

We are developing our proprietary, versatile vaccine platform to stimulate the immune system to target and attack cancer cells and infectious diseases. This vaccine platform is based on specially designed strains of the bacterium *Listeria monocytogenes*. We believe that the combination of proprietary strains of *Listeria* with specific cancer antigens, such as Mesothelin, has the potential to harness the power of the immune system to selectively attack malignant cells.

In September 2004, pre-clinical efficacy and safety data for our cancer immunotherapy technology were published in the *Proceedings of the National Academy of Sciences*, or PNAS. The paper described studies in which experimental vaccines based on a proprietary attenuated *Listeria* strain were engineered to express tumor antigens. These vaccines were shown to elicit therapeutic anti-tumor responses in vaccinated tumor-bearing mice, including prolonged survival and tumor regression. In addition, our strain demonstrated an over one thousand-fold reduction in toxicity when compared to unmodified *Listeria*.

In the experiments described in the PNAS paper, a strain was systematically selected from our library of genetically defined attenuated *Listeria*. In comparison to other strains, the optimized strain was cleared more rapidly in vivo and also showed significantly higher safety margins while preserving immunologic potency. When used at comparable doses to the unmodified *Listeria*, the optimized strain generated equivalent immune responses, yet could be administered at higher doses, resulting in more potent T-cell responses than those produced using unmodified *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.

We have begun pre-clinical development of a strain of proprietary attenuated *Listeria* for use in treating colorectal cancer that has metastacized to the liver. Pre-clinical experiments suggest that our *Listeria* strain selectively stimulates an anti-cancer immune response in the liver. We have commenced toxicology studies and plan to file an investigational new drug application, or IND, with the FDA by the end of 2005.

In April 2004, we entered into an agreement with MedImmune for the development of a therapeutic vaccine based on our *Listeria* platform and utilizing the EphA2 protein, which is expressed in a number of solid tumors and is proprietary to MedImmune. Under the terms of the agreement, MedImmune is responsible for clinical testing, manufacturing and commercialization of any product resulting from the collaboration. We received an up-front payment and are participating in the development of the therapeutic vaccine. The agreement also provides for us to receive development funding, as well as milestone payments and royalties on future product sales.

In December 2003, we licensed from The Johns Hopkins University rights to Mesothelin, an antigen that is prevalently expressed in pancreatic and ovarian tumors. 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. We have begun pre-clinical development of a pancreatic cancer vaccine in collaboration with investigators at The Johns Hopkins University. We intend to continue to pursue partnership opportunities with companies having proprietary antigen targets and to pursue our own products.

In addition to our *Listeria* vaccine platform, we are developing vaccines for infectious diseases based on an application of our Helinx technology, called KBMA, in which we inhibit infectivity, but maintain metabolic activity, of selected pathogens. In so doing, we hope our product candidates can attain the potency typically found in live viral and bacterial vaccines, but with the safety advantages of killed vaccines. In July 2004, we were awarded a $3.8 million grant from the National Institutes of Health to develop an anthrax vaccine based on the KBMA platform technology with the potential for greater potency than currently available vaccines. Anthrax is an infectious disease caused by the spore-forming bacterium

Bacillus anthracis. The only licensed human anthrax vaccine, called anthrax vaccine absorbed or AVA, was developed in the late 1950 s and has limited efficacy.

Blood Safety

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

The INTERCEPT Blood System for platelets has received CE Mark approval and is being marketed by Baxter in several countries in Europe. Baxter will need to complete validation studies and obtain regulatory and reimbursement approvals in some individual European countries to market the product in those countries, which include the United Kingdom, France and Germany. The level of additional product testing 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 and France. We expect these studies to be funded largely by Baxter pursuant to the terms of our restructured collaboration agreements in February 2005. We expect that decisions to purchase substantial quantities of product may be deferred until completion of the additional European clinical and experience studies. In certain countries, including the United Kingdom, France and Germany, the system must be approved for purchase or use by a specific governmental or non-governmental (such as the Paul Ehrlich Institute in Germany) entity or entities. Baxter has informed us that it has been notified by a regulatory body in France that the review of the platelet system marketing application is complete and the agency has granted authorization for the preparation, distribution and therapeutic use of the product. Commercial availability of the product in France is subject to publication of a decree in the Official Journal to register INTERCEPT platelets and define their specifications, reimbursement approval and successful completion of certain laboratory studies.

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 analysis of the clinical trial data, under the direction of an independent contract research organization, to determine if apparent differences between treatment groups in the category of respiratory adverse events reported in the study were attributable to inconsistent event reporting. The assessments of primary patient records, by an independent panel of expert physicians, showed no statistically significant differences in respiratory adverse advents between test and control groups when applying consistent diagnostic criteria. In addition, application of objective criteria used to assess specific respiratory adverse events also showed no statistically significant differences between 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 respiratory events. A summary of the initial results of the analysis was filed in a current report on Form 8-K with the SEC on July 17, 2004. We plan to submit with Baxter a final report of the analysis to the FDA for review. The final report is expected to include conclusions from an independent panel of experts. We expect the FDA may request an additional Phase III clinical trial to evaluate the hemostatic efficacy and safety of INTERCEPT platelets, prepared using our final commercial product design, compared to conventional platelets. Data from the additional analyses and a supplemental clinical trial would need to be submitted to the FDA before we could complete our regulatory submission.

We completed the last of three planned Phase III clinical trials of the INTERCEPT Blood System for plasma in 2004. The primary and secondary efficacy endpoints of the trial for therapeutic plasma exchange

were met. The study showed no statistically significant differences in overall adverse events between the two patient groups. Certain adverse events were more prevalent in the test group and are being further evaluated. There were no statistical differences in frequency of related serious adverse events reported. We are continuing development activities in this program at a reduced rate. As a result of our June 2004 realignment, we have prioritized submission with Baxter of an application for a CE Mark approval in Europe, which we hope to submit by late 2005, ahead of any regulatory filing efforts in the United States.

In September 2003, we terminated Phase III clinical trials of our red blood cell system due to the detection of antibodies in two patients. We are evaluating the antibodies detected in the trial and are investigating whether process changes could prevent antibody formation and allow the modified red blood cell system to undergo clinical trials. We announced several findings related to these evaluations in December 2004 at the annual meeting of the American Society of Hematology, including a modified pathogen inactivation process for red blood cells, which may reduce the immunoreactivity of the treated red blood cells. We continue to evaluate the feasibility of re-entering clinical trials in the United States with this modified process.

Additional development activities for the INTERCEPT programs will require significant resources beyond those presently available. Moreover, such activities will take significant time to complete and may not be successful. Particularly in light of our restructured collaboration with Baxter, we will have greater responsibility for further development funding than we have had previously. We may be unable to fund future development and commercialization efforts without significant capital from other sources.

Collaborations

Agreement with MedImmune. In April 2004, we 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 in this collaboration using our *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. We are responsible for pre-clinical development of a therapeutic vaccine candidate. We are receiving development funding and may receive contingent milestone payments and royalties on future product sales.

Collaborations with The Johns Hopkins University. We have a collaborative research agreement with The Johns Hopkins University, or JHU, relating to our program for use of our *Listeria* vaccine platform in combination with the Mesothelin antigen for treatment of pancreatic and breast cancer. A second collaborative research agreement with JHU focuses on our use of our *Listeria* vaccine platform as a treatment for colorectal cancer metastasized to the liver. We have a license from JHU for certain uses of Mesothelin and options to license other technologies of JHU complementary to our *Listeria* vaccine platform. Those collaborations are expected to aid us in both pre-clinical and early stage development of our *Listeria* products. However, our collaborations with JHU are not exclusive as to indication or field and would allow us to enter into collaborative agreements with other parties at our future discretion.

Restructured Agreements with Baxter for Commercialization of the INTERCEPT Blood System. Prior to February 2005, Baxter and we shared development expenses for the INTERCEPT Blood Systems for platelets and red blood cells under our development and commercialization agreements. The agreements provided for us to be solely responsible for funding development expenses for the INTERCEPT Blood System for plasma. Under the agreements, Baxter has been responsible for manufacturing and marketing the INTERCEPT Blood System for platelets, which is approved for sale in some countries in Europe. The agreements provided for us 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. We did not recognize revenue from product sales during the year ended December 31, 2004, because revenue sharing

payments were being withheld by Baxter due to a dispute over the timing of repayment of a loan to us from Baxter Capital Corporation.

Baxter and we entered into agreements in February 2005 that reaffirmed our previous agreements in certain respects and modified them in other respects. Under the February 2005 agreements, Baxter retained the right and responsibility to market and sell, sometimes referred to as commercialization rights for, the INTERCEPT Blood System for platelets worldwide. Baxter also retains commercialization rights for the INTERCEPT Blood System for plasma in all parts of the world except North America. Baxter retains these commercialization rights, in general, through 2006. Baxter has options to extend these commercialization rights for successive two-year periods after 2006. Baxter s commercialization rights for the platelet system are subject to the rights of BioOne in Japan and certain other Asian countries under agreements previously signed with BioOne. If a transaction is completed with BioOne for the plasma system in such countries, Baxter s rights will also be subject to that agreement.

Pursuant to the February 2005 agreements, we gained commercialization rights to the INTERCEPT Blood System for plasma in North America and commercialization rights to the INTERCEPT Blood System for red blood cells worldwide. As to such regions, our license to Baxter terminated and Baxter granted us a license to any Baxter technology included in the plasma system and the red blood cell system, respectively.

In addition, if Baxter does not exercise its option to extend its commercialization rights after 2006, or any subsequent two-year period, we will gain the commercialization rights for the products and countries that Baxter then holds.

Under the February 2005 agreements, Baxter remains solely responsible for sales and marketing expenses for the products/countries as to which it maintains commercialization rights. For 2005 and 2006, Baxter has agreed to fund $13.1 million of expenses for INTERCEPT Blood System sales and marketing and for activities directed toward CE Mark approval of the plasma system. It has also agreed to furnish specified levels of personnel to conduct sales and marketing of the INTERCEPT Blood System for platelets and, upon approval, plasma in Europe. Our agreements with Baxter provide for a joint Cerus/Baxter governance committee that will set sales and marketing strategy for Baxter to execute.

We will have responsibility for sales and marketing expenses for any products/countries for which we gain commercialization rights. We have the sole discretion, however, to determine the extent of such expenditures.

So long as Baxter retains commercialization rights for the platelet system or plasma system in particular countries, Baxter will continue to manufacture that system for sale in such countries. Baxter and we will continue to share revenues from such sales generally according to the terms of the previous agreements. The agreements continue to provide for us to receive approximately 33.5% of revenue from sales of platelet system disposables after each party is reimbursed for its cost of goods to the extent cost exceeds specific amounts, and for us to receive 75% and Baxter to receive 25% of revenue from sales of plasma system disposables, in each case after each party is reimbursed for its cost of goods and a specified percentage, not to exceed 12% of revenue, is retained by Baxter for marketing and administrative expenses.

For those countries where we gained commercialization rights under the February 2005 agreements, Baxter has agreed to manufacture systems and components, on a cost-plus basis, until 2009. If Baxter elects to extend its commercialization rights beyond December 31, 2008, the manufacturing period will be extended until approximately two years after the expiration of Baxter s extended commercialization rights. As the agreements do not require Baxter to manufacture in an FDA-approved facility, additional validation steps may be required of us 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.

The February 2005 agreements require us to pay royalties to Baxter on INTERCEPT Blood System products sold by us, or our affiliates, pursuant to our commercialization rights. The royalties vary by product, and do not exceed 10% of net sales for any products.

Our arrangement with Baxter to equally fund development work for the platelet system and the red blood cell system also was terminated by the February 2005 agreements. Commencing January 1, 2005, each company bears its own expenses relating to discussions with the FDA to gain clarity on the remaining steps in the U.S. regulatory process for the platelet system. Following such discussions, Baxter may continue to retain its commercialization rights for the platelet system in North America provided it funds 100% of development expenses directed toward obtaining FDA approval and also commits to specified levels of sales and marketing expenditures for the product. Under the agreements, Baxter ceases to have any obligation to fund development of the red blood cell system.

Cerus remains 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 the plasma system. Baxter has agreed to cooperate with Cerus 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 Cerus expense.

Agreements with BioOne. In June 2004, Baxter and we 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 BioOne s receipt of regulatory approval in each of those countries. In July 2004 and October 2004, Baxter and we each received up-front payments of $10.0 million. The agreement also provides for contingent milestone payments and royalties on future product sales, which would be shared equally by Baxter and us.

In December 2004, Baxter and we 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, we received a payment of $3.0 million from BioOne. Our right to retain the up-front payment is not contingent upon completion of the definitive agreement. Terms specified in the letter of intent are subject to the parties entering into a definitive agreement. Under the letter of intent, Baxter and we are restricted from negotiating a similar agreement with other parties before April 2005.

Cooperative Agreements with the Armed Forces of the United States. In February 2001, we were awarded a $3.5 million cooperative agreement by the Army Medical Research Acquisition Activity division of the Department of Defense. In September 2002, May 2003, January 2004 and July 2004, we were awarded additional funding of $6.5 million, $6.2 million, $5.5 million and $3.7 million, respectively, all of which was awarded to continue funding of projects to develop our pathogen inactivation technologies to improve the safety and availability of blood that may be used by the Armed Forces for medical transfusions. Under the conditions of the agreements, we are conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites, which are of particular concern to the Armed Forces. This funding also supports advanced development of our blood safety technologies.

In October 2004, we received a $6.2 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.

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 our INTERCEPT Blood Systems 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 pre-clinical 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 system components for development and commercial purposes.

Under our agreements with Baxter, we are responsible for developing and delivering our proprietary compounds to Baxter for incorporation into the final system configuration. Baxter is responsible for manufacturing or supplying the disposable units, such as blood storage containers and related tubing, as well as any device associated with the inactivation process. This arrangement applies both to the current supply for clinical trials and, if applicable regulatory approvals are obtained, the future commercial supply, subject to certain limitations on Baxter s obligations under the February 2005 agreements.

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

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

Marketing, Sales and Distribution

The market for our pathogen inactivation systems is dominated by a small number of blood collection organizations in the United States. In many countries of Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations blood and blood components supply. In Europe, the largest markets for our products are in Germany, the United Kingdom and France. Decisions on product adoption are centralized in the United Kingdom. In Germany, decisions on product adoption are expected to be on a blood center-by-blood center basis. We have not received in-country approvals to market our platelet system in Germany or the United Kingdom, and certain additional activities are required before we can market the system in France.

For logistical and financial reasons, the transfusion industry has not always integrated new technologies into their processes, even those with the potential to improve the safety of the blood supply. Our products may require significant changes to our potential customers space and staffing requirements and require significant capital investment. Even if our product candidates receive regulatory approval for commercial sale, physicians, patients and healthcare payors may not believe that the benefits of using our systems justify their additional cost. 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. Our products may be inappropriate for certain patients, which could reduce the potential market size. In addition, healthcare professionals may require further safety information or additional studies before adopting our products. Together with Baxter and BioOne, 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.

Baxter is responsible for the marketing, sales and distribution of the platelet system in the United States, Europe and other regions not covered by our agreement with BioOne in Asia. Baxter also is responsible for the marketing sales and distribution of the plasma system in Europe and other countries, excluding North America and the regions for which we expect to enter into a definitive agreement with BioOne, upon marketing approval of the product. We currently have a small scientific affairs group that helps support the commercialization efforts of Baxter and BioOne; however, we do not intend to develop our own independent marketing and sales organization and expect to continue to rely on third parties to market and sell the INTERCEPT Blood System.

Under our April 2004 agreement, MedImmune would be responsible for sales and marketing of any products resulting from our collaboration. It will take a long time for us to complete pre-clinical development, clinical trials and regulatory approval for one or more of our other 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 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 pathogen inactivation methods that are either on the market, or in development. The INTERCEPT Blood System is designed for use in blood centers, to integrate with current blood collection, processing and storage procedures. Competing products in development or currently on the market, such as solvent-detergent treated plasma, use centralized processing that takes the blood product away from the blood center. The INTERCEPT Blood System is designed for use with single units of blood products. Some potential competitors utilize a pooling process prior to pathogen inactivation, which significantly increases the risk of cross-contamination by pathogens that are not inactivated. There are currently no competitors that have pathogen inactivation methods approved or in Phase II or Phase III clinical trials for platelets. 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 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 price, product supply and marketing and sales capability. In addition, the length of time required for products to be developed and to receive regulatory and, in some cases, reimbursement approval is an important competitive factor. We believe that the INTERCEPT Blood System competes favorably with respect to these factors, although there can be no assurance that it will be able to continue to do so. The biopharmaceutical field is characterized by rapid and significant technological changes. Accordingly, our success will depend in part on our ability to respond quickly to medical and technological changes through the development and introduction of new products. Product development involves a high degree of risk, and there can be no assurance that our product development efforts will result in any commercially successful products.

Patents, Licenses and Proprietary Rights

Our success depends in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on the proprietary rights of us. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. As of December 31, 2004, we owned approximately 64 issued or allowed United States patents and approximately 64 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

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

The 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) pre-clinical laboratory and animal tests, (ii) submission to the FDA of an investigational device exemption (for medical devices) or an investigational new drug application (for drugs or biologics) for human clinical testing, which must become effective before human clinical trials may begin, (iii) appropriate tests to show the product s safety, (iv) adequate and well-controlled human clinical trials to establish the product s safety and efficacy for its intended indications, (v) submission to the FDA of a PMA 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 is planning to file one or more investigational new drug, or IND, 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 premarket 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. Many individual European countries require additional in-country studies to support an approval to market the products in such countries.

Baxter is using a modular process for its PMA application for the INTERCEPT Blood System for platelets. The content, order and submission timing of the modules must be approved by the FDA, and a modular PMA application cannot be approved until all modules have been submitted to, reviewed by and accepted by the FDA.

In addition to the regulatory requirements applicable to our INTERCEPT products, there are regulatory requirements applicable to our prospective customers, the blood centers that process and distribute blood and blood products. Blood centers and others will likely be required to obtain approved

license supplements from the FDA before using 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 our INTERCEPT pre-clinical 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 medical products and services. The trend toward managed health care in the United States and other countries and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may all affect the prices for our products.

Employees

As of February 28, 2005, we had 83 employees, 56 of whom were engaged in research and development and 27 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.

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.

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

Except for the INTERCEPT Blood System for platelets, which has received CE Mark approval and regulatory approval in certain countries in Europe, we have no products that have received regulatory approval for commercial sale and are being marketed. Our product candidates are in various stages of development, and we face the risks of failure inherent in developing medical devices and biotechnology products based on new technologies. Our products must satisfy rigorous standards of safety and efficacy before the FDA and international regulatory authorities can approve them for commercial use. We must provide the FDA and foreign regulatory authorities with pre-clinical, clinical and manufacturing data that demonstrate our products are safe, effective and in compliance with government regulations before the products can be approved for commercial sale.

In 2002, the INTERCEPT Blood System for platelets received CE Mark approval in Europe. We will need to complete validation studies and obtain reimbursement approvals in some individual European countries to market our products in those countries. Further clinical studies, ranging from small-scale experience studies to larger randomized clinical trials, will be conducted in some regions and countries, such as the Netherlands and France. We expect these studies to be funded by sources other than us. We expect that decisions to purchase substantial quantities of product may be deferred until completion of the additional study or studies in the respective country. In certain countries, including the United Kingdom, France and Germany, the system must be approved for purchase, reimbursement or use by a specific governmental or non-governmental entity or entities (such as the Paul Ehrlich Institute in Germany) in order for it to be adopted by a specific customer. The level of additional product testing varies by country, but could take a long time to complete.

We completed our Phase III clinical trial of the INTERCEPT Blood System for platelets in the United States in March 2001 and have submitted data from this trial, along with several other modules of our pre-market approval application, to the FDA. Based on discussions with the FDA, we performed an additional analysis of the clinical trial data, under the direction of an independent contract research organization, to determine if apparent differences between treatment groups in the category of respiratory adverse events reported in the study were attributable to inconsistent event reporting. The assessments of primary patient records showed no statistically significant differences between groups. These assessments differed from adverse events drawn from the patient records, which showed statistically significant differences in specific respiratory events. We plan to submit a final report of the analysis to the FDA for review. The final report is expected to include conclusions from an independent panel of experts. If the results of this analysis are satisfactory to the FDA, we expect the FDA to request a supplemental clinical trial to evaluate the hemostatic efficacy and safety of INTERCEPT platelets, prepared using our final commercial product design, 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 our 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 in the United States. We are preparing a CE Mark application for regulatory approval in Europe. We have not submitted any applications for regulatory approval of the INTERCEPT Blood

System for plasma in the United States or any other regions. In some countries, we may be required to perform an additional clinical study using the commercial configuration of the system in order to obtain regulatory approval.

As a result of the termination of Phase III clinical trials of our red blood cell system due to the detection of antibodies in two patients, we are conducting additional research activities on our red blood cell system to determine if the system can be reconfigured to reduce antibody formation and potentially undergo clinical testing. We may not be successful in this research. If we are successful, we expect that we will be required to initiate our clinical studies in Phase I trials in healthy volunteers before potentially progressing to later-stage clinical trials. If we are unsuccessful in developing a modified red blood cell system that can complete clinical testing, then we may never realize a return on our development expenses incurred to date in this program.

Clinical trials in particular are expensive and have a high risk of failure. Any of our product candidates may fail in the testing phase or may not achieve results sufficient to attain market acceptance, which could prevent us from achieving profitability.

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

Our 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 pre-clinical 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 pre-clinical 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. Naturally-occurring *Listeria* is a bacterium that is a human pathogen that can cause serious illness. Although our vaccine candidates use proprietary, modified strains of *Listeria* that are designed to be substantially less able to cause illness in humans, our vaccine candidates may not be accepted for clinical testing unless we successfully complete a number of pre-clinical safety studies. We have not yet discussed our pre-clinical development and clinical trial plans for our vaccine candidates with the FDA. Because our vaccine candidates use a novel platform, the FDA may require studies that we have not anticipated. In addition, we intend to contract with third-party manufacturers to produce our vaccines for clinical testing. We have not yet manufactured vaccines for clinical testing, and may not be successful in doing so. We may experience numerous unforeseen events during, or as a result of, the pre-clinical research and development process that could delay or prevent clinical testing, regulatory approval and commercialization of our potential products.

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

In Europe, the Baxter sales and marketing organization has made only modest progress in countries where the INTERCEPT Blood System for platelets has been fully approved for sale. Despite our CE Mark approval, we have 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. For logistical and financial

reasons, the transfusion industry has not always integrated new technologies into their processes, even those with the potential to improve the safety of the blood supply. Our products may require significant changes to our potential customers space and staffing requirements and require significant capital investment. Even if our product candidates receive regulatory approval for commercial sale, physicians, patients and healthcare payors may not believe that the benefits of using our systems justify their additional cost. 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. Our products may be inappropriate for certain patients, which could reduce the potential market size. In addition, some potential customers have indicated that further safety information or additional studies would be required before adopting our products. 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 our INTERCEPT products fail to achieve market acceptance, we may never become profitable.

Our products 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 United States local, state and federal regulatory authorities and by foreign regulatory bodies. These regulations are wide-ranging and govern, among other things:

- development;
- testing;
- manufacturing;
- labeling;
- storage;
- premarket clearance or approval;
- sales and distribution;
- use standards and documentation;
- 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 our INTERCEPT 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. If BPAC were to recommend approval of one or more of our products, the FDA would not necessarily be required to 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 may be subject to review by the Recombinant DNA Advisory Committee of the National Institutes of Health, which could delay intiation of clinical trials.

Even if our product candidates receive approval for commercial sale, their marketing and manufacturing will be subject to continuing FDA and other regulatory requirements, such as requirements to comply with Good Manufacturing Practice. The failure to comply with these requirements could result in enforcement action, which could harm our business. 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 our INTERCEPT products in clinical trials, it is possible that harmful effects of our products not observed in clinical and pre-clinical testing could be discovered 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. For example, the FDA is considering implementing standards for the recovery and survival of stored platelets. Some platelets are consumed in our pathogen inactivation process. If we are unable to meet new or existing FDA standards for the recovery and survival of platelets, we may be unable to market our platelet system in the United States. We cannot predict the impact of adverse governmental regulation that might arise from future legislative or administrative action.

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

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

Regulatory agencies may limit the uses, or indications, for which any of our products are approved. For example, we believe that our INTERCEPT 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, the blood centers that process and distribute blood and blood products. Blood centers and others will likely be required to obtain approved license supplements from the FDA or European regulatory authorities before using products processed with our pathogen inactivation systems. This requirement or regulators delays in approving these supplements may deter some blood centers from using our products. Blood centers that do submit supplements may face disapproval or delays in approval that could provide further delay or deter them from using our products. The regulatory impact on potential customers could slow or limit the potential sales of our products.

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

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

A small number of customers will determine market acceptance of our INTERCEPT products.

Even if our products receive regulatory approval to be commercialized and marketed, due to the intense market concentration, failure to properly market, price or sell our products to any of these large customers could significantly diminish potential product revenue. The market for our pathogen inactivation systems in the United States is 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 nations blood and blood components supply. In Europe, the largest markets for our products are in Germany, the United Kingdom and France. Decisions on product adoption are centralized in the United Kingdom. In Germany, decisions on product adoption are expected to be on a blood center-by-blood center basis. We have not received in-country approvals to market our platelet system in Germany or the United Kingdom, and certain additional activities are required before we can market the system in France. The National Blood Service has indicated that significant additional steps will need to be completed before it considers implementation of our platelet system in England. If we do not receive approvals to market our products in these countries, or if the products are not adopted in these countries, our potential product revenue in Europe will be significantly decreased.

We rely on Baxter for regulatory support, manufacturing, marketing and sales of our INTERCEPT products.

The success of our INTERCEPT Blood Systems depends significantly on Baxter s performance under our agreements.

- *We rely on Baxter for regulatory support.* If Baxter fails to perform satisfactorily in this function, our CE Mark filing for our plasma system and our efforts to seek FDA approval of our platelet system will be significantly delayed. Delays or inabilities to complete regulatory filings and obtain approvals will delay or prevent us from being able to recognize sales of our products and attain profitability. Under our agreements with Baxter, commercialization rights for the platelet system will transfer to us if Baxter does not commit to additional development and marketing obligations following further discussions with the FDA. Baxter may not decide to make such additional commitments. In such event, we would become fully responsible for regulatory activities for the platelet system in the United States, and our efforts to seek regulatory approval of the platelet system may be further delayed.

- *We rely on Baxter for manufacturing and supplying components of our systems for platelets and plasma.* Under the terms of our agreements, Baxter is currently responsible for manufacturing and supplying certain components and devices for development and commercial use. If Baxter fails to design or deliver an adequate supply of components, we could be required to identify other third-party component manufacturers. We cannot assure you that we would be able to identify such manufacturers on a timely basis or enter into contracts with such manufacturers on reasonable terms, if at all. Any delay in the availability of devices or 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. Because of low sales volumes and other reasons, Baxter s costs to manufacture commercial components for the INTERCEPT Blood System for platelets are greater than we previously anticipated and may continue to rise. This will reduce our potential revenue from European platelet system sales.

- *We rely on Baxter for marketing, sales and distribution.* We currently have a small scientific affairs group that helps support Baxter s marketing organization; however, we do not intend to develop our own independent marketing and sales organization and expect to continue to rely on Baxter to market and sell the INTERCEPT Blood System for platelets and plasma in certain countries. If Baxter fails to perform, we could be required to find another marketing, sales and distribution partner or develop these capabilities ourselves. We may not be able to find a suitable partner on favorable terms or on a timely basis, if at all. Developing marketing, sales and distribution capabilities ourselves would increase our costs and would delay commercialization of our pathogen inactivation systems. Under our agreements with Baxter, commercialization rights for the platelet system will transfer to us if Baxter does not commit to additional development and marketing obligations following further discussions with the FDA. Baxter may decide not to make such additional commitments. In such event, we would become fully responsible for marketing, sales and distribution of the platelet system in the United States, and our efforts to commercialize our platelet system may be further delayed.

We may be required to identify and enter into agreements with third parties to manufacture, market and sell our products.

Baxter s current manufacturing, marketing and sales responsibilities for our platelet and plasma systems have limited terms. Baxter is no longer obligated to provide marketing and sales for our plasma system in the United States or manufacturing, marketing and sales for our red blood cell system at all. We expect that we will need to identify third parties to provide these services and we do not intend to develop these capabilities ourselves. It may be difficult to enter into these types of agreements with third parties on reasonable terms. It will be time-consuming for other manufacturers to develop the capability to manufacture our INTERCEPT products economically and to gain regulatory approval to do so for commercial use. We expect that our need for manufacturers other than Baxter for certain products and regions will delay our efforts to commercialize our products in those regions.

We rely on BioOne for commercialization of our platelet system in some regions in Asia.

Baxter and we have licensed rights to commercialization of the INTERCEPT Blood System for platelets in Japan and certain other countries to BioOne. BioOne is solely responsible for obtaining regulatory approvals, marketing and selling the products in those countries. Because we have a minority investment interest in BioOne, we lack the ability to significantly influence BioOne, and are dependent on BioOne s performance to realize revenue from our platelet system 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 revenue from platelet system sales in those countries. In December 2004, Baxter and we

entered into a letter of intent with BioOne for commercialization of the INTERCEPT Blood System for plasma in the same countries. We expect to enter into a definitive agreement in 2005. Subject to the definitive agreement, we will similarly depend on BioOne for commercialization of our plasma system in those countries. BioOne will need to raise additional capital to be successful in commercializing our products.

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

Significant clinical trial delays would impair our ability to commercialize our products and could allow competitors to bring more products to market before we do. Some of our clinical trials involve patient groups with rare medical conditions, which has in the past made, and may continue to make, it difficult to identify and enroll a sufficient number of patients to complete the trials on time. Future clinical trials may be sponsored or co-sponsored with a development partner or other organizations, which would reduce our ability to control the clinical trial plan and execution. Other factors, including the unavailability of blood products or delays in the supply of clinical product material, could also delay our clinical trials. Our product development costs will increase if we have additional delays in testing or approvals.

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

We expect our products to encounter significant competition. Our INTERCEPT 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 through the development and introduction of new products. Product development is risky and uncertain, and we cannot assure you that we will develop our products successfully. Competitors products or technologies may make our products obsolete or non-competitive before we are able to generate any significant revenue. Competitors or potential competitors may have substantially greater financial and other resources than we have. They may also have greater experience in pre-clinical testing, human clinical trials and other regulatory approval procedures.

Several companies are developing technologies that are, or in the future may be, the basis for products that will directly compete with or reduce the market for our pathogen inactivation systems. A number of companies are specifically focusing on alternative strategies for pathogen inactivation in platelets and plasma. In Europe, several companies, including Grifols, Octapharma AG and Maco Pharma International GmbH, are developing or have developed commercial systems to treat fresh frozen plasma. Navigant, a wholly-owned subsidiary of Gambro, Inc., is developing a pathogen inactivation system for platelets.

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 INTERCEPT Blood System for platelets 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. Some are large pharmaceutical companies, such as Sanofi-Aventis and Bristol-Myers Squibb, which have greater experience and resources in product development, pre-clinical 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 Dendreon Corporation, Antigenics, Inc., Cell Genesys, Inc. and CancerVax, Inc., that have cancer vaccine programs that are in more advanced stages of development than ours.

Because our INTERCEPT product candidates have not been manufactured on a commercial scale, we face manufacturing uncertainties that could limit their commercialization. If our third-party manufacturers fail to produce our compounds satisfactorily and in sufficient quantities, we may incur delays, shortfalls and additional expenses.

Our INTERCEPT product candidates, including many of the components, have never been manufactured on a commercial scale. We intend to use third-party manufacturers to produce commercial quantities of the chemical compounds to be used in our products. These compounds have never been produced in commercial quantities. We have an agreement with a manufacturer to produce commercial quantities of amotosalen, which is the compound used in our platelet and plasma systems. We currently do not have any other third-party manufacturing agreements in place for commercial production of other compounds 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 systems and plasma systems in certain regions. Baxter intends to rely on third parties to manufacture and assemble some of the system components, many of which are customized and have not been manufactured on a commercial scale. Baxter has not produced the pathogen inactivation systems in commercial quantities and may not be able to manufacture and assemble them, or do so economically. In the United States, studies related to the platelet system disposable and compound manufacturing need to be completed and included in FDA submissions before the FDA would consider the applications for approval.

Baxter has advised us that it intends to purchase certain key components of the pathogen inactivation systems from a limited number of suppliers. Contracts for the long-term supply of certain components have not yet been signed. While we believe there are alternative suppliers for these components, it would be expensive and time-consuming to establish additional or replacement suppliers for these components. If Baxter were unable to find adequate suppliers for these components, we may be required to redesign the systems, which could lead to additional testing and clinical trials. If we were required to redesign the products, our development costs would increase, and our programs could be delayed significantly.

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

If we fail to develop commercial versions of our 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. The system disposables and instruments we used in many of our pre-clinical studies and clinical trials were prototypes of those to be used in the final products. As a result, we plan to perform studies, both pre-clinical and clinical, to demonstrate the acceptability of the commercial configuration and the equivalence of the prototype and the commercial design. However, regulatory authorities may require us to perform additional studies, both pre-clinical and clinical, using the commercial versions of the systems, which may increase our expenses and delay the commercialization of our products.

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

We will need to establish a sufficient shelf life for the components of our blood safety products before the FDA and other regulatory authorities will approve additional INTERCEPT products for sale.

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

We will need to develop and test additional configurations of our blood safety products to address the entire market.

In the United States, our efforts to develop our INTERCEPT Blood System for platelets have focused almost entirely on apheresis platelets collected on Baxter s automated collection platform. Apheresis platelets are platelets that are collected from a single donor using an automated collection machine. Currently, we estimate that the majority of platelets used in the United States are collected by apheresis, with the remainder prepared from pooled random donor platelets. Blood centers in the United States preparing random donor platelets may be reluctant to switch to apheresis collection, and the FDA may require us to make our systems compatible with random donor platelets. In order to develop a platelet pathogen inactivation system compatible with random donor platelets, we will need to perform additional product development and testing, including clinical trials. These development activities would increase our costs significantly, and may not be successful. In addition, FDA regulations limit to four hours the time from pooling to transfusion to minimize the proliferation of bacterial contamination in the pooled product. As a result, most pooling occurs in hospitals. Our platelet system is designed for use in blood centers, not hospitals, and is intended to permit storage and transfusion of treated platelets for up to five days after pooling. The FDA s time limit between pooling and transfusion currently precludes the use of our system with pooled random donor platelets. Although our system is designed to reduce the risk of bacterial contamination, we cannot predict whether the FDA would remove this process time constraint to allow our system to be used with pooled random donor platelets, and we have not yet made a formal request for the FDA to do so.

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

Our system for plasma is being developed and tested for plasma collected through automated equipment. Although we have used a system for plasma collected from whole blood in clinical trials, we currently do not intend to develop this as a commercial product. Plasma collected through automated equipment currently represents the minority of plasma units collected in many of our potential markets, including the United States and most of Western Europe. Unless these markets convert to automated

plasma collection, we will need to develop and test additional configurations of these systems in order to address the majority of the market for plasma in these countries.

We may be liable if our products harm people.

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and products. We may be liable if any of our products cause injury, illness or death. Although we will have completed rigorous pre-clinical 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 pre-clinical or clinical testing. We maintain product liability insurance, but do not know whether the insurance will provide adequate coverage against potential liabilities. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products.

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

We may never achieve a profitable level of operations. To date, we have engaged primarily in research and development. Our development and general and administrative expenses have resulted in substantial losses each year since our inception, including net losses of $57.2 million in 2002, $58.3 million in 2003 and $31.2 million in 2004. As of December 31, 2004, we had an accumulated deficit of approximately $319.7 million. Except for the INTERCEPT Blood System for platelets, 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 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. Additionally, we may need to reduce or stop further investment in specific research and development activities if we are unable to obtain additional capital or if any of our development programs are determined by us to be uneconomical. A product or program may be determined to be uneconomical if the commercial opportunity is insufficient to justify the investment required to develop and market the products or for other reasons. It is our objective that our spending in support of research, development and commercialization of the INTERCEPT programs be balanced with development funding for such programs from third parties. As a result, further product development and commercialization of the INTERCEPT Blood Systems will take longer than we previously anticipated and our objective of balancing spending with outside funding will reduce our ability to accelerate development in the future. 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 the United States government, completion of a definitive agreement with BioOne for the commercialization of the INTERCEPT Blood System for plasma in Asia, 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.

To date, we have been awarded $31.6 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.

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. Our patents expire at various dates between 2009 and 2018. 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.

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

Our research and development activities involve the controlled use of hazardous materials, including certain hazardous chemicals, radioactive materials and infectious pathogens, such as HIV and hepatitis

viruses. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with regulatory requirements, we cannot eliminate the risk of accidental contamination or injury. If an accident occurs, we could be held liable for any damages that result.

The market price of our stock may be highly volatile.

The market prices for our securities and those of other emerging medical device and biotechnology companies have been, and may continue to be, volatile. For example, during the period from January 1, 2003 to December 31, 2004, the closing sale price of our common stock as quoted on the Nasdaq National Market fluctuated from a low of $1.85 to a high of $21.72. Announcements may have a significant impact on the market price of our common stock. Such announcements may include:

- biological or medical discoveries;
- technological innovations or new commercial services by us or our competitors;
- developments concerning proprietary rights, including patents and litigation matters;
- regulatory developments in both the United States and foreign countries;
- status of development partnerships;
- public concern as to the safety of new technologies;
- general market conditions;
- comments made by analysts, including changes in analysts estimates of our financial performance; and
- quarterly fluctuations in our revenue and financial results.

The stock market has from time to time experienced extreme price and volume fluctuations, which have particularly affected the market prices for emerging biotechnology and medical device companies, and which have often been unrelated to the operating performance of such companies. These broad market fluctuations may adversely affect the market price of our common stock.

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

We, and certain of our 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, 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 achieve and maintain effective internal controls in accordance with Section 404 of this Act could have a material adverse effect on our stock price.

We are completing our documentation and testing of our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which 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. During the course of our testing, we may identify deficiencies in internal controls. In addition, 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 2. *Properties*

We lease approximately 21,400 square feet for our main office facility in Concord, California. The lease for this facility extends through August 2007, with an option to renew for an additional three-year period. We also have leases for approximately 17,400 square feet, approximately 9,900 square feet and approximately 31,808 square feet at three facilities, all of which contain laboratory and office space and are located near our main building in Concord. These leases extend through June 2009, January 2006 and October 2006 (with five one-year renewal options and an option for us to terminate the lease with nine month s notice any time), respectively. 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 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.

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.

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, 2003:		
First Quarter	21.75	5.29
Second Quarter	13.20	7.23
Third Quarter	8.23	4.55
Fourth Quarter	5.49	3.40
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

On February 28, 2005, the last reported sale price of our common stock on the Nasdaq National Market was $4.45 per share. On February 28, 2005, we had approximately 238 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, 2004. The information presented should be read in conjunction with the financial statements and notes included elsewhere herein. The selected financial data for the periods prior to the financial statements included herein are derived from audited financial statements.

	Years Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 13,911	$ 9,665	$ 8,490	$ 4,535	$ 1,851
Operating expenses:					
Research and development	27,651	52,484	56,421	48,247	34,823
General and administrative	10,225	11,016	11,346	10,166	7,160
Restructuring	2,861				
Total operating expenses	40,737	63,500	67,767	58,413	41,983
Loss from operations	(26,826)	(53,835)	(59,277)	(53,878)	(40,132)
Net interest income (expense)	(4,327)	(4,432)	2,085	4,611	4,099
Loss before income taxes	(31,153)	(58,267)	(57,192)	(49,267)	(36,033)
Provision for income taxes				(100)	
Net loss	$ (31,153)	$ (58,267)	$ (57,192)	$ (49,367)	$ (36,033)
Net loss per share-basic and diluted(1)	$ (1.41)	$ (3.01)	$ (3.61)	$ (3.27)	$ (2.75)
Shares used in computing net loss per share-basic and diluted(1)	22,143	19,367	15,833	15,105	13,086

	As of December 31, 2004 (in thousands)	2003	2002	2001	2000
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 95,334	$ 110,010	$ 64,318	$ 123,461	$ 90,260
Working capital	23,782	49,819	50,486	108,606	78,884
Total assets	102,078	118,463	72,947	128,260	94,161
Loan and interest payable to a related party	39,000	55,834			
Capital lease obligations, less current portion			16	51	84
Redeemable convertible preferred stock				5,000	5,000
Accumulated deficit	(319,707)	(288,554)	(230,287)	(173,095)	(123,728)
Total stockholders equity	21,489	52,528	56,169	106,755	76,921

(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. We have been unprofitable since inception and, as of December 31, 2004, had an accumulated deficit of approximately $319.7 million. Except for the INTERCEPT Blood System for platelets, for which the European Union approved issuance of a CE Mark, all of our product candidates are in the research and development stage. We have not received significant revenue to date from product sales. We must conduct significant research, development, pre-clinical and clinical evaluation, commercialization and regulatory compliance activities on these product candidates that, together with anticipated general and administrative expenses, are expected to result in substantial losses at least until after commercialization of additional products. Our ability to achieve a profitable level of operations in the future will depend on our ability to successfully complete development and obtain additional regulatory approvals of, and on the abilities of our partners and us to commercialize and achieve market acceptance of, blood safety and immunotherapy product candidates. We may never achieve a profitable level of operations.

Critical Accounting Policies and Management Estimates

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

assumptions or conditions. We record accrued liabilities for certain contract research activities, including clinical trials, pre-clinical safety studies, external laboratory studies and development activities performed by Baxter. Some of those accrued liabilities are based on estimates because billings for these activities may not occur on a timely basis consistent with the performance of the services.

We believe the following critical accounting policies, which have been reviewed by our Audit Committee, affect our more significant judgments and estimates used in the preparation of our financial statements:

- Revenue and research and development expenses Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the project are incurred. Revenue related to at risk milestones specified under development contracts is recognized as the milestones are achieved. License fees and payments for achieved milestones are non-refundable and are not subject to future performance. We 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.

- Long-term investments We account for our investment in equity securities of BioOne under the cost method. Our use of the cost method is based, in part, on our determination that we lack ability to exert significant influence over BioOne. Under the cost method, we also assess whether there is impairment of the value of the asset as of each period-end.

- Accrued liabilities We record accrued liabilities for certain contract research activities, including clinical trials, pre-clinical safety studies, external laboratory studies and development activities performed by Baxter, for research and development services performed. Some of those accrued liabilities are based on estimates because billings for these activities may not occur on a timely basis consistent with the performance of the services.

Collaborations

Agreement with MedImmune. In April 2004, we 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 in this collaboration using our *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. We are responsible for pre-clinical development of a therapeutic vaccine candidate. We are receiving development funding and may receive contingent milestone payments and royalties on future product sales. In May 2004, we 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 pre-clinical development period.

Restructured Agreements with Baxter for Commercialization of the INTERCEPT Blood System. Prior to February 2005, we shared development expenses with Baxter for the INTERCEPT Blood Systems for platelets and red blood cells under our development and commercialization agreements. The agreements

provided for us to be solely responsible for funding development expenses for the INTERCEPT Blood System for plasma. We recognized $751,000 of development funding under these agreements during the year ended December 31, 2004. Under the agreements, Baxter has been responsible for manufacturing and marketing the INTERCEPT Blood System for platelets, which is approved for sale in some countries in Europe. The agreements provided for us 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. We did not recognize revenue from product sales during the year ended December 31, 2004, because revenue sharing payments were being withheld by Baxter due to a dispute over the timing of repayment of a loan to us from Baxter Capital.

We entered into agreements with Baxter in February 2005 that reaffirmed our previous agreements in certain respects and modified them in other respects. Under the February 2005 agreements, Baxter retained the right and responsibility to market and sell, sometimes referred to as commercialization rights for, the INTERCEPT Blood System for platelets worldwide. Baxter also retains commercialization rights for the INTERCEPT Blood System for plasma in all parts of the world except North America. Baxter retains these commercialization rights, in general, through 2006. Baxter has options to extend these commercialization rights for successive two-year periods after 2006. Baxter s commercialization rights for the platelet system are subject to the rights of BioOne in Japan and certain other Asian countries under agreements previously signed with BioOne. If a transaction is completed with BioOne for the plasma system in such countries, Baxter s rights will also be subject to that agreement.

Pursuant to the February 2005 agreements, we gained commercialization rights to the INTERCEPT Blood System for plasma in North America and commercialization rights to the INTERCEPT Blood System for red blood cells worldwide. As to such regions, our license to Baxter terminated and Baxter granted us a license to any Baxter technology included in the plasma system and the red blood cell system, respectively.

In addition, if Baxter does not exercise its option to extend its commercialization rights after 2006, or any subsequent two-year period, we will gain the commercialization rights for the products and countries that Baxter then holds.

Under the February 2005 agreements, Baxter remains solely responsible for sales and marketing expenses for the products/countries as to which it maintains commercialization rights. For 2005 and 2006, Baxter has agreed to fund $13.1 million of expenses for INTERCEPT Blood System sales and marketing and for activities directed toward CE Mark approval of the plasma system. It has also agreed to furnish specified levels of personnel to conduct sales and marketing of the INTERCEPT Blood System for platelets and, upon approval, plasma in Europe. Our agreements with Baxter provide for sales and marketing strategy surrounding Baxter s commercialization rights to be set by a joint Cerus/Baxter governance committee.

We will have responsibility for sales and marketing expenses for any products/countries for which we gain commercialization rights. We have the sole discretion, however, to determine the extent of such expenditures.

So long as Baxter retains commercialization rights for the platelet system or plasma system in particular countries, Baxter will continue to manufacture that system for sale in such countries. Baxter and we will continue to share revenues from such sales generally according to the terms of the previous agreements. The agreements continue to provide for us to receive approximately 33.5% of revenue from sales of platelet system disposables after each party is reimbursed for its cost of goods to the extent cost exceeds specific amounts, and for us to receive 75% and Baxter to receive 25% of revenue from sales of plasma system disposables, in each case after each party is reimbursed for its cost of goods and a specified percentage, not to exceed 12% of revenue, is retained by Baxter for marketing and administrative expenses.

For those countries where we gained commercialization rights under the February 2005 agreements, Baxter has agreed to manufacture systems and components, on a cost-plus basis, until 2009. If Baxter elects to extend its commercialization rights beyond December 31, 2008, the manufacturing period will be extended until approximately two years after the expiration of Baxter s extended commercialization rights. As the agreements do not require Baxter to manufacture in an FDA-approved facility, additional validation steps may be required of us 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.

The February 2005 agreements require us to pay royalties to Baxter on INTERCEPT Blood System products sold by us, or our affiliates, pursuant to our commercialization rights. The royalties vary by product, and do not exceed 10% of net sales for any products.

Our arrangement with Baxter to equally fund development work for the platelet system and the red blood cell system also was terminated by the February 2005 agreements. Commencing January 1, 2005, each company bears its own expenses regarding our discussions with the FDA to gain clarity on the remaining steps in the U.S. regulatory process for the platelet system. Following such discussions, Baxter may continue to retain its commercialization rights for the platelet system in North America provided it funds 100% of development expenses directed toward obtaining FDA approval and also commits to specified levels of sales and marketing expenditures for the product. Under the agreements, Baxter ceases to have any obligation to fund development of the red blood cell system.

Cerus remains 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 the plasma system. Baxter has agreed to cooperate with Cerus 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 Cerus expense.

Under a separate agreement with Baxter Capital relating to the $50.0 million loan and accrued interest, we 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 has agreed to accept these payments in full satisfaction of the loan obligation, and Baxter Capital and we have dismissed the related legal actions.

Agreements with BioOne. In June 2004, Baxter and we 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 BioOne s receipt of regulatory approval in each of those countries. In July 2004 and October 2004, Baxter and we each received up-front payments of $10.0 million. We are deferring the up-front payments and recognizing amounts ratably as development funding over the expected period to regulatory approval. The agreement also provides for contingent milestone payments and royalties on future product sales, which would be shared equally by Baxter and us. We recognized $1.7 million of revenue under this agreement during the year ended December 31, 2004.

In December 2004, Baxter and we 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, we received a payment of $3.0 million from BioOne. Our right to retain the up-front payment is not contingent upon completion of the definitive agreement. The payment is recorded as deferred revenue as of December 31, 2004. Terms specified in the letter of intent are subject to the parties entering into a definitive agreement. Under the letter of intent, Baxter and we are restricted from negotiating a similar agreement with other parties before April 2005.

Cooperative Agreements with the Armed Forces of the United States. In February 2001, we were awarded a $3.5 million cooperative agreement by the Army Medical Research Acquisition Activity division of the Department of Defense. In September 2002, May 2003, January 2004 and July 2004, we were awarded additional funding of $6.5 million, $6.2 million, $5.5 million and $3.7 million, respectively, all of which was awarded to continue funding of projects to develop our pathogen inactivation technologies to improve the safety and availability of blood that may be used by the Armed Forces for medical transfusions. Under the conditions of the agreements, we are conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites, which are of particular concern to the Armed Forces. This funding also supports advanced development of our blood safety technologies.

In October 2004, we received a $6.2 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 awards fund work to be performed through November 2006.

Agreement with Kirin. In January 2001, we entered into a collaborative agreement with the Pharmaceutical Division of Kirin to develop and market products for stem cell transplantation based on our Helinx technology. Under the terms of the agreement, we will jointly develop the products with Kirin. We received an initial license fee of $1.0 million. The license fee is being deferred and recognized as development funding ratably over the development period. We do not expect to receive additional funding from Kirin. Although the agreement calls for Kirin to fund all development expenses for the Asia-Pacific region and a portion of our development activities toward obtaining product approval in the United States, no such development activities co-funded by Kirin are currently ongoing. Upon product approval, Kirin has exclusive rights to market the products in the Asia-Pacific region, including Japan, China, Korea and Australia, and we would receive a specified share of product revenue, including a royalty and reimbursement of our cost of goods. We retain all marketing rights for the rest of the world, including the United States and Europe.

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

Results of Operations

2004 Compared with 2003

Revenue. For the year ended December 31, 2004, milestone and development funding from Baxter increased 89% to $0.8 million from $0.4 million for 2003. The increase was primarily due to the termination of the Phase III red blood cell clinical trials 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. As a result of the February 2005 agreements, we do not expect to recognize additional development funding from Baxter for the platelet and red blood cell programs. 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. In 2005, we expect revenue from the Armed Forces for blood safety programs to be less than amounts recognized in 2004; however, we expect to recognize additional revenue from the Armed Forces for the research and development of vaccines for biodefense and cancer. 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 $52,000 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 has been deferred until payment of such revenue is expected to be collected. As a result of the resolution of the loan dispute with Baxter Capital in February 2005, we expect to recognize product sales revenue in 2005. The INTERCEPT Blood System for platelets is currently undergoing validation studies and regulatory reimbursement review in many European countries. We do not expect sales of the system in Europe to be significant at least until the system is approved for sale and reimbursement rates 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, pre-clinical safety studies, manufacturing development and other laboratory studies. 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. We anticipate that our research and development expenses for 2005 will decrease relative to 2004, primarily as a result of our June 2004 restructuring. 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 pre-clinical and clinical study results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects; see Risk Factors above.

General and Administrative Expenses. General and administrative expenses decreased 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. We expect our general and administrative expenses to decrease in 2005 relative to 2004 as a result of our restructuring.

Restructuring. On June 30, 2004, we announced that we realigned our operations to increase resources for our program to develop therapeutic vaccines against cancer and infectious diseases and reduce expenditures for our blood safety programs and administrative expenses. 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 this restructuring.

Net Interest Expense. Net interest expense was $4.3 million for 2004, down slightly from $4.4 million in 2003. In 2004 and 2003, we accrued interest expense at 12% on the $50.0 million loan from Baxter Capital. In 2005, we expect interest expense to be reduced significantly as a result of the February 2005 resolution of the loan dispute with Baxter Capital. We will accrue interest expense 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. We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain.

2003 Compared with 2002

Revenue. For the year ended December 31, 2003, milestone and development funding from related parties decreased to $0.4 million from $5.0 million for 2002. Amounts recognized in 2003 were from Baxter for development of the INTERCEPT Blood System for platelets, whereas in 2002 a $5.0 million milestone payment from Baxter was earned upon regulatory approval of the INTERCEPT Blood System for platelets in Europe. Development funding from Baxter was 4% of total revenue for 2003.

Development funding from other sources, which included Kirin and the NMDP, decreased 16% to $0.6 million for 2003 from $0.7 million for 2002. Revenue recognized from Kirin in 2003 was from the up-front payment that was deferred and recognized ratably over the development period. There is no development activity co-funded by Kirin currently ongoing or planned at Cerus. Development funding from the NMDP was 5% of total revenue for 2003. Development funding from Kirin was 1% of total revenue for 2003.

Revenue from government grants and cooperative agreements increased 214% to $8.6 million for 2003 from $2.7 million for 2002. The increase was primarily due to a $5.7 million increase in program expenditures under the cooperative agreements with the Armed Forces of the United States, most of this increase supporting research and development applicable to the INTERCEPT Blood System. During 2003, we also recognized $0.4 million of revenue from six separate research grants from the National Institutes of Health.

We recognized $52,000 and $3,000 of product sales revenue in 2003 and 2002, respectively, from sales of the INTERCEPT Blood System for platelets in Europe.

Research and Development Expenses. Research and development expenses decreased 7% to $52.5 million for 2003 from $56.4 million for 2002. The decrease was primarily due to reduced development spending by Baxter and also to the termination of Phase III clinical trials in the red blood cell program in September 2003. Our total research and development costs included $45.6 million for the INTERCEPT Blood System program and $6.9 million for all other programs for 2003, and $48.7 million for the INTERCEPT Blood System program and $7.7 million for all other programs for 2002.

General and Administrative Expenses. General and administrative expenses decreased 3% to $11.0 million for 2003 from $11.3 million for 2002. The slight decrease was primarily due to the employment of fewer administrative personnel and consultants in 2003.

Net Interest Income (Expense). Net interest expense was $4.4 million for 2003 compared to net interest income of $2.1 million for 2002. We received proceeds from a $50.0 million loan from Baxter Capital in January 2003 and recorded $5.9 million of related interest expense in 2003. Interest income from

investments was $1.5 million for 2003 compared to $2.1 million for 2002. The decrease was primarily due to reduced yields on investments as a result of declines in market interest rates.

Liquidity and Capital Resources

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

At December 31, 2004, we had cash, cash equivalents and short-term investments of $95.3 million. Net cash used in operating activities was $12.7 million in 2004, compared to $58.6 million in 2003. The reduction in net cash used in operating activities was primarily due to the net loss of $31.2 million, favorable changes in other operating balances of $16.0 million, including an increase in deferred revenue associated with the BioOne and MedImmune agreements and a reduction in amounts receivable from the United States government, and non-cash operating expenses, including $2.2 million of depreciation expense. Net cash provided by investing activities of $28.5 million resulted primarily from sales and maturities of short-term investments being greater than the combination of purchases of short-term investments and the $1.2 million investment we made in BioOne equity securities during the period. Working capital decreased to $23.8 million at December 31, 2004, from $49.8 million at December 31, 2003, primarily due to the net loss for 2004.

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 has 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 have agreed to dismiss all related legal actions.

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 December 31, 2006. 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 6,000,000 shares of common stock with gross proceeds, calculated for registration statement purposes, of $57.8 million under the shelf registration statement. We have no current commitments to offer or sell additional securities pursuant to this registration statement.

Commitments

Our commitments are as follows:

	Payments Due by Period, from December 31, 2004				
	Total (in thousands)	Less than 1 year	1-3 years	4-5 years	After 5 years
Contractual obligations:					
Loan and interest payable to a related party	$ 39,716	$ 34,500	$ 5,216	$	$
Minimum purchase requirements	150	50	100		
License fees and sponsored research	377	231	126	20	
Operating leases	2,936	1,281	1,205	450	
Total contractual cash obligations	$ 43,179	$ 36,062	$ 6,647	$ 470	$

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, 2004 (dollar amounts in thousands):

	Fair Value	Weighted Average Interest Rate
Cash equivalents (0 90 days)	$ 35,480	2.10 %
Short-term investments (91 days 1 year)	2,690	1.89 %
Short-term investments (1 3 years)	53,151	2.35 %
Total investments	$ 91,321	

Item 8. *Financial Statements and Supplementary Data*

Our financial statements, together with related notes and report 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, 2004, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2004.

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

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and the chief executive officer and 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, 2004, is discussed in the Management s Report on Internal Control Over Financial Reporting included on page 45.

Item 9B. *Other Information*

2004 Executive Bonuses. On January 18, 2005, the Compensation Committee of our Board of Directors awarded the following bonuses to our executive officers in connection with the achievement in fiscal year 2004 of specified corporate milestones and individual goals:

Executive Officer	Position	Bonus Compensation
Claes Glassell	President and Chief Executive Officer	$ 175,000
David N. Cook	Vice President, Research and Development	$ 121,784
Laurence M. Corash	Vice President, Medical Affairs	$ 146,692
William J. Dawson	Vice President, Finance, and Chief Financial Officer	$ 34,635
Howard G. Ervin	Vice President, Legal Affairs	$ 88,346

PART III

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

Information regarding our directors and officers, and the compliance of certain reporting persons with Section 16(a) of the Securities Exchange Act of 1934, as amended, will be set forth under the captions Election of Directors, Management, Section 16(a) Beneficial Ownership Reporting Compliance and Code of Ethics in our definitive proxy statement for use in connection with the annual meeting of stockholders to be held on June 6, 2005 (the Proxy Statement) and is incorporated herein by reference. We intend to file the Proxy Statement with the Securities and Exchange Commission within 120 days after the end of our 2004 fiscal year.

Item 11. *Executive Compensation*

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

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

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

Item 13. *Certain Relationships and Related Transactions*

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

Item 14. *Principal Accountant Fees and Services*

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

PART IV

Item 15. *Exhibits 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.
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.

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, 2004. 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, 2004, 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, 2004. 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, 2004, 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, 2004, 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, 2004, 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, 2004 and 2003, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2004 of Cerus Corporation and our report dated March 11, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Walnut Creek, California
April 29, 2005

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, 2004 and 2003, and the related statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2004. 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, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004 in conformity with U. S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Walnut Creek, California
March 11, 2005

CERUS CORPORATION
BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2004	2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,169	$ 23,165
Short-term investments	56,165	86,845
Accounts receivable from related parties	4	8
Accounts receivable and other current assets	4,533	5,736
Total current assets	99,871	115,754
Furniture and equipment at cost:		
Laboratory and office equipment	5,768	5,578
Leasehold improvements	7,173	7,300
	12,941	12,878
Less accumulated depreciation and amortization	11,994	10,325
Net furniture and equipment	947	2,553
Long-term investments	1,175	
Other assets	85	156
Total assets	$ 102,078	$ 118,463
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,280	$ 1,487
Accounts payable to a related party	196	3,156
Current loan and interest payable to a related party	34,500	55,834
Accrued compensation and related expenses	2,749	2,075
Accrued contract research expenses	587	1,200
Other accrued expenses	1,471	1,550
Deferred revenue	13,217	614
Deferred gain on loan settlement	22,089	
Current portion of capital lease obligations		19
Total current liabilities	76,089	65,935
Long term debt payable to a related party	4,500	
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value: issuable in series; 3,327 shares issued and outstanding at December 31, 2004 and 2003; aggregate liquidation preference of $9,496 at December 31, 2004 and 2003	9,496	9,496
Common stock, $0.001 par value; 50,000,000 shares authorized: 22,210,674 and 22,060,249 shares issued and outstanding at December 31, 2004 and 2003, respectively	22	22
Additional paid-in capital	332,002	331,564
Accumulated other comprehensive loss	(324)	
Accumulated deficit	(319,707)	(288,554)
Total stockholders equity	21,489	52,528
Total liabilities and stockholders equity	$ 102,078	$ 118,463

See accompanying notes.

CERUS CORPORATION
STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Years ended December 31,		
	2004	**2003**	**2002**
Revenue:			
Milestone and development funding, related parties	$ 751	$ 398	$ 5,002
Development funding, other	3,436	624	747
Government grants and cooperative agreements	9,724	8,591	2,738
Product sales		52	3
Total revenue	13,911	9,665	8,490
Operating expenses:			
Research and development	27,651	52,484	56,421
General and administrative	10,225	11,016	11,346
Restructuring	2,861		
Total operating expenses	40,737	63,500	67,767
Loss from operations	(26,826)	(53,835)	(59,277)
Interest income (expense):			
Interest income	1,631	1,482	2,095
Interest expense	(5,987)	(5,904)	(10)
Other income (expense), net	29	(10)	
Net interest income (expense)	(4,327)	(4,432)	2,085
Net loss	$ (31,153)	$ (58,267)	$ (57,192)
Net loss per share basic and diluted	$ (1.41)	$ (3.01)	$ (3.61)
Shares used in computing net loss per share basic and diluted	22,143,476	19,366,727	15,833,403

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	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2001	3,327	$ 9,496	15,737,165	$ 16	$ 270,338	$	$ (173,095)	$ 106,755
Conversion of Series A preferred stock to common stock			129,968		5,000			5,000
Issuance of common stock for services			1,000		33			33
Issuance of common stock under stock option and employee stock purchase plans			81,530		1,573			1,573
Net loss							(57,192)	(57,192)
Balances at December 31, 2002	3,327	9,496	15,949,663	16	276,944		(230,287)	56,169
Issuance of common stock, net of expenses of $236			6,000,000	6	54,058			54,064
Issuance of common stock under stock option and employee stock purchase plans			110,586		562			562
Net loss							(58,267)	(58,267)
Balances at December 31, 2003	3,327	9,496	22,060,249	22	331,564		(288,554)	52,528
Issuance of common stock under stock option and employee stock purchase plans			150,425		438			438
Net change in unrealized loss on investments						(324)		(324)
Net loss							(31,153)	(31,153)
Balances at December 31, 2004	3,327	$ 9,496	22,210,674	$ 22	$ 332,002	$ (324)	$ (319,707)	$ 21,489

See accompanying notes.

CERUS CORPORATION
STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended December 31, 2004	2003	2002
Operating activities			
Net loss	$ (31,153)	$ (58,267)	$ (57,192)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,152	3,291	2,497
Issuance of common stock for services			33
Stock-based compensation to employees	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 from a related party	4	(25)	(20)
Accounts receivable and other current assets	1,203	(2,852)	(1,311)
Other assets	71	(4)	36
Accounts payable to a related party	(2,960)	(5,382)	3,509
Accrued interest payable to a related party	5,986	5,897	
Accounts payable	(207)	(535)	(1,198)
Accrued compensation and related expenses	674	(401)	(158)
Accrued contract research expenses	(613)	(354)	(1,242)
Other accrued expenses	(849)	131	(398)
Deferred revenue	12,642	(104)	(209)
Net cash used in operating activities	(12,728)	(58,615)	(55,653)
Investing activities			
Purchases of furniture and equipment	(594)	(297)	(5,032)
Proceeds from sale of equipment		10	
Investments in BioOne Corporation	(1,237)		
Purchases of short-term investments	(76,835)	(191,695)	(100,157)
Sale of short-term investments	95,725	83,089	53,033
Maturities of short-term investments	11,466	63,644	64,199
Net cash provided by (used in) investing activities	28,525	(45,249)	12,043
Financing activities			
Net proceeds from issuance of common stock	226	54,626	1,573
Proceeds from loan payable to a related party		50,000	
Payments on capital lease obligations	(19)	(32)	(31)
Net cash provided by financing activities	207	104,594	1,542
Net increase (decrease) in cash and cash equivalents	16,004	730	(42,068)
Cash and cash equivalents, beginning of period	23,165	22,435	64,503
Cash and cash equivalents, end of period	$ 39,169	$ 23,165	$ 22,435
Supplemental disclosures:			
Interest paid	$ 1	$ 7	$ 10
Accounts receivable from a related party applied to loan payable to a related party	$	$ 63	$

See accompanying notes.

CERUS CORPORATION
NOTES TO FINANCIAL STATEMENTS
December 31, 2004

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. The Company has not received material revenue from product sales, and substantially all revenue recognized by the Company to date has resulted from the Company s 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, pre-clinical 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.

Development funding is in the form of payments made (i) by Baxter to the Company to reimburse the Company for development spending in excess of the levels determined by Baxter and the Company and (ii) by 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. Up-front payments received in the year ending December 31, 2004, totaling $1,000,000 and $13,000,000 from MedImmune and BioOne, respectively, were deferred and are being recognized ratably over the periods to which the payments relate. During the year ended December 31, 2002, the Company recognized $5,000,000 of milestone revenue from Baxter upon European regulatory approval for the platelet system. There were no other milestones or up-front payments recognized during the years ended December 31, 2004, 2003 and 2002.

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, pre-clinical 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 cooperative 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 fair value based on quoted market prices. The Company reports the amortization of any discount or premium resulting from the purchase of debt securities as a component of interest income. The available-for-sale securities recorded at amounts that approximate fair value at December 31, 2004 and 2003, totaled $91,644,000 and $105,223,000, respectively.

Unrealized gains and losses at December 31, 2004 and 2003, are reported in accumulated other comprehensive income. There were no realized gains or losses or declines in value judged to be other than temporary for the years then ended. The cost of securities sold is based on the specific identification method. Substantially all of the Company s cash, cash equivalents and short-term investments are maintained by three major financial institutions.

Furniture and Equipment

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

Stock-Based Compensation

The Company accounts for employee stock options in accordance with Accounting Principles Board Opinion No. 25 (APB 25), including Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation: An Interpretation of APB No. 25, (FIN 44), and has adopted the disclosure only alternative described in Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation, as amended by Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure (FAS 123).

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

	2004	2003	2002
	(in thousands, except per share data)		
Net loss:			
As reported	$ (31,153)	$ (58,267)	$ (57,192)
Add:			
Stock-based compensation expense included in reported net loss, net of related tax effects	292		
Less:			
Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	2,404	8,300	15,491
Pro forma	$ (33,265)	$ (66,567)	$ (72,683)
Net loss per share basic and diluted, as reported	$ (1.41)	$ (3.01)	$ (3.61)
Net loss per share basic and diluted, pro forma	$ (1.50)	$ (3.44)	$ (4.59)

Income Taxes

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

Net Loss Per Share Basic and Diluted

The Company calculates basic and diluted earnings per share in accordance with Statement of Financial Accounting Standards No. 128, Earnings Per Share (FAS 128). Under FAS 128, basic earnings per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the assumed conversion of all dilutive securities, such as options, warrants, convertible debt and convertible preferred stock. Common stock equivalent shares of 332,700 from preferred stock and 4,293,861 from stock options are not included as the effect is anti-dilutive.

Comprehensive 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 comprised unrealized holding losses on the Company s available-for-sale securities, which were reported separately in stockholders equity.

Guarantee and Indemnification Arrangements

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

Disclosures About Segments of an Enterprise

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, 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. Segment information for the years ended December 31, 2004, 2003 and 2002, is presented below (in thousands):

	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

	2002	
	Revenue	Operating Loss
Blood safety programs	$ 7,531	$ 53,759
Immunotherapies	959	5,518
Totals	$ 8,490	$ 59,277

New Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board 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 instrumens 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 June 15, 2005. The Company is required to adopt FAS 123R no later than the beginning of the third quarter of 2005. FAS 123R permits public companies to adopt its requirements using either the modified prospective method or the modified restrospective 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 base on the stock compensation amounts included in its previous pro forma disclosures. The Company has not yet determined which method it will elect beginning July 1, 2005. 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 loss and net loss per common share in 2004 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.

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 pre-clinical 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 pre-clinical 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 pre-clinical development period, estimated to be 24 months. The Company recognized $1,559,000 of revenue under this agreement in the year ended December 31, 2004.

Restructured Agreements with Baxter, a Related Party of the Company

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, 2004 and 2003, the Company recognized development funding of $751,000 and $398,000, respectively, under these agreements. Also under these agreements, the Company recognized $5,000,000 of milestone revenue from Baxter in June 2002 upon European regulatory approval for the platelet system. 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 $52,000 and $3,000 in the years ended December 31, 2003 and 2002, respectively. Recognition of product sales revenue has been 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. Under the February 2005 agreements, Baxter retains the right and responsibility to market and sell (commercialization rights) the platelet system worldwide. Baxter also retains commercialization rights for the plasma system in all parts of the world except North America. Baxter retains these commercialization rights, in general, through 2006. Baxter has options to extend these commercialization rights for successive two-year periods after 2006. Baxter s commercialization rights for the platelet system are subject to the rights of BioOne in Japan and certain other Asian countries under agreements previously signed with BioOne. If a transaction is completed with BioOne for the plasma system in such countries, Baxter s rights will also be subject to that agreement.

Pursuant to the February 2005 agreements, the Company gained commercialization rights to the plasma system in North America and commercialization rights to the red blood cell system worldwide. As to such regions, the Company s license to Baxter terminated and Baxter granted the Company a license to any Baxter technology included in the plasma system and the red blood cell system, respectively.

In addition, if Baxter does not exercise its option to extend its commercialization rights after 2006, or any subsequent two-year period, the Company will gain the commercialization rights for the products and countries that Baxter then holds.

Under the February 2005 agreements, Baxter remains solely responsible for sales and marketing expenses for the products/countries as to which it maintains commercialization rights. For 2005 and 2006, Baxter has 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. It has 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 provide for sales and marketing strategy surrounding Baxter s commercialization rights to be set by a joint Cerus/Baxter governance committee.

The Company will have responsibility for sales and marketing expenses for any products/countries for which it gain commercialization rights. The Company has the sole discretion, however, to determine the extent of such expenditures.

So long as Baxter retains commercialization rights for the platelet system or plasma system in particular countries, Baxter will continue to manufacture that system for sale in such countries. Baxter and

the Company will continue to share revenues from such sales generally according to the terms of the previous agreements. The agreements continue to provide for the Company to receive approximately 33.5% of revenue from sales of platelet system disposables after each party is reimbursed for its cost of goods to the extent cost exceeds specific amounts, and for the Company to receive 75% and Baxter to receive 25% of revenue from sales of plasma system disposables, in each case after each party is reimbursed for its cost of goods and a specified percentage, not to exceed 12% of revenue, is retained by Baxter for marketing and administrative expenses.

For those countries where the Company gained commercialization rights under the February 2005 agreements, Baxter has agreed to manufacture systems and components, on a cost-plus basis, until 2009. If Baxter elects to extend its commercialization rights beyond December 31, 2008, the manufacturing period will be extended until approximately two years after the expiration of Baxter s extended commercialization rights. As the agreements do not require Baxter to manufacture in an FDA-approved facility, additional validation steps may be required 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.

The February 2005 agreements require the Company to pay royalties to Baxter on INTERCEPT Blood System products sold by the Company or its affiliates pursuant to its commercialization rights. The royalties vary by product, and do not exceed 10% of net sales for any product.

The Company s arrangement with Baxter to equally fund development work for the platelet system and the red blood cell system also was terminated by the February 2005 agreements. Commencing January 1, 2005, each company bears its own expenses regarding discussions with the FDA to gain clarity on the remaining steps in the U.S. regulatory process for the platelet system. Following such discussions, Baxter may continue to retain its commercialization rights for the platelet system in North America provided it funds 100% of development expenses directed toward obtaining FDA approval and also commits to specified levels of sales and marketing expenditures for the product. Under the agreements, Baxter ceases to have any obligation to fund development of the red blood cell system.

The Company remains 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 the plasma system. Baxter has 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.

Agreements with BioOne

In April 2004, the Company made a $93,000 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 and other corporations. Because the Company s investment represented greater than 20% of BioOne s common stock, the Company accounted for this investment under the equity method for the three months ended June 30, 2004. During this period, the Company recorded a loss of $62,000 representing its share of BioOne s net losses for that period.

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. The up-front payments are 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 $1,696,000 of revenue under this agreement during the year ended December 31, 2004.

In July 2004, the Company made an additional $1.1 million investment in BioOne equity securities. As a result of dilution from additional concurrent third party investments in BioOne, the Company holds less than 20% of the outstanding voting securities of BioOne and accounts for this investment under the cost method. The Company has determined that there is no impairment of this investment as of December 31, 2004.

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. The Company s right to retain the up-front payment is not contingent upon completion of the definitive agreement. The payment is recorded as deferred revenue as of December 31, 2004. Terms specified in the letter of intent are subject to the parties entering into a definitive agreement. Under the letter of intent, Baxter and the Company are restricted from negotiating a similar agreement with other parties before April 2005.

Cooperative Agreements with the Armed Forces of the United States

In February 2001, the Company was awarded a $3.5 million cooperative agreement by the Army Medical Research Acquisition Activity division of the Department of Defense. In September 2002 and May 2003, January 2004 and July 2004, the Company was awarded additional funding of $6.5 million, $6.2 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 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 which are of particular concern to the Armed Forces. This funding also supports advanced development of the Company s blood safety technologies. The Company recognized $8,869,000, $8,200,000 and $2,526,000 of revenue under these agreements during the years ended December 31, 2004, 2003 and 2002, respectively.

In October 2004, the Company received a $6.2 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 $828,000 under this award. This advance payment was recorded as deferred revenue as of December 31, 2004.

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 $38,000, $481,000 and $538,000 in development funding from the NMDP during the years ended December 31, 2004, 2003 and 2002, respectively.

3. Investments

Available-for-sale securities comprised the following at December 31:

	2004 Adjusted Cost (in thousands)	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. government investments:				
Original maturities less than one year	$ 1,005	$	$ (19)	$ 986
Original maturities one year or greater	44,390	1	(293)	44,098
Total government investments	45,395	1	(312)	45,084
Corporate debt investments:				
Original maturities less than one year	1,709		(5)	1,704
Original maturities one year or greater	9,061	2	(10)	9,053
Total corporate investments	10,770	2	(15)	10,757
Total short-term investments	$ 56,165	$ 3	$ (327)	$ 55,841

	2003 Adjusted Cost (in thousands)	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. government investments:				
Original maturities less than one year	$ 7,239	$	$	$ 7,239
Original maturities one year or greater	46,861			46,861
Total government investments	54,100			54,100
Corporate debt investments:				
Original maturities less than one year	2,999			2,999
Original maturities one year or greater	29,746			29,746
Total corporate investments	32,745			32,745
Total short-term investments	$ 86,845	$	$	$ 86,845

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

In January 2003, the Company received proceeds from a $50.0 million loan from Baxter Capital, 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 February 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 has 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, the Company has 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 includes a current payable of $34.5 million, which was paid in February 2005 to Baxter Capital, a $770,000 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 will be 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 will accrue interest at 8%.

5. Commitments and Contingencies

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

Capital lease obligations represent the present value of future rental payments under capital lease agreements for laboratory and office equipment. The original cost and accumulated amortization on the equipment under capital leases was $142,000 and $142,000, respectively, at December 31, 2003. There were no capital lease obligations outstanding as of December 31, 2004.

Future minimum payments under operating leases are as follows:

Year ending December 31,	**Operating Leases (in thousands)**
2005	$ 1,281
2006	666
2007	539
2008	300
2009	150
Total minimum lease payments	$ 2,936

Rent expense for office facilities was $1,219,000, $1,344,000 and $1,219,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

On December 8, 2003, a class action complaint was filed in the United States District Court for the Northern District of California against the Company and certain of its present and former directors and officers. On December 10, 2003, a second action was filed in the same Court against the same defendants. Both actions were brought on behalf of a purported class of persons who purchased the Company s publicly traded securities between October 25, 2000, and September 3, 2003. The complaints alleged that the defendants violated the federal securities laws by making certain 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 A Redeemable Convertible Preferred Stock

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

Series B Preferred Stock

Baxter holds 3,327 shares of the Company s Series B preferred stock. The holder of Series B preferred stock has no voting rights, except with respect to the authorization of any class or series of stock having preference or priority over the Series B preferred stock as to voting, liquidation or conversion or with respect to the determination of fair market value of non-publicly traded shares received by the holder of Series B stock in the event of a liquidation, or except as required by Delaware law. At any time, the holder may convert each share of Series B preferred stock into 100 common shares. If all shares of Series B preferred stock were converted to common stock, 332,700 shares would be issued, which represents 1.5% of the outstanding common shares of the Company at December 31, 2004. 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 4,780,000 shares of common stock for issuance under its 1999 Equity Incentive Plan (the 1999 Plan). The 1999 Plan provides for grants of ISOs to employees and NSOs, stock bonuses and restricted stock purchase awards to employees, directors and consultants of the Company. The option term is ten years.

Stock-Based Compensation

The Company has elected to follow APB 25 and related interpretations, including FIN 44, in accounting for its employee stock awards because, as discussed below, the alternative fair value accounting provided for under FAS 123 requires the use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, because the exercise price of the Company s employee common stock options equals or exceeds the market price of the underlying common stock on the grant date (for certain Company common stock grants), no compensation expense is recorded.

Pro forma information regarding net loss and net loss per share is required by FAS 123, and has been determined as if the Company had accounted for its employee stock options and employee stock purchase plan under the fair value method of that Statement. The fair value for these options and shares was estimated at the date of grant using a Black-Scholes model with the following weighted-average assumptions for the years ended December 31:

	Stock Option Plans			Employee Stock Purchase Plan		
	2004	2003	2002	2004	2003	2002
Expected volatility	.602	.884	.637	.612	.885	.637
Risk-free interest rate	3.37 %	2.96 %	2.80 %	1.63 %	2.24 %	1.50 %
Expected life of the option (years)	5	5	5	0.5	0.5	0.5

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

Activity under the stock option plans is set forth below:

	Number of Options Outstanding	Weighted Average Exercise Price per Share
Balances at December 31, 2001	2,181,711	$ 30.686
Granted	1,162,871	42.597
Cancelled	(131,408)	43.672
Exercised	(54,084)	17.692
Balances at December 31, 2002	3,159,090	$ 34.703
Granted	1,026,092	5.944
Cancelled	(607,234)	32.353
Exercised	(24,286)	2.682
Balances at December 31, 2003	3,553,662	$ 27.029
Granted	2,078,348	2.599
Cancelled	(1,332,487)	28.612
Exercised	(5,880)	0.544
Balances at December 31, 2004	4,293,643	$ 14.749

The weighted average fair value of options granted during the years ended December 31, 2004, 2003 and 2002 was $1.173, $3.416 and $19.650 per share, respectively. At December 31, 2004, options to purchase 1,100,065 shares of common stock were available for future grant.

	Options Outstanding			Options Vested	
Range of Exercise Prices	Number of Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$ 1.950 2.160	193,090	9.61	$ 2.065	13,377	$ 2.141
$ 2.280 2.360	658,500	9.49	$ 2.281		
$ 2.390 2.390	519,575	9.50	$ 2.390	75	$ 2.390
$ 2.400 3.140	251,544	6.36	$ 2.802	123,137	$ 2.735
$ 3.250 3.250	517,090	9.33	$ 3.250	90,006	$ 3.250
$ 3.520 6.750	479,245	8.74	$ 4.819	210,523	$ 4.952
$ 7.000 21.000	446,774	5.93	$ 12.689	355,729	$ 13.938
$21.060 38.188	632,797	6.00	$ 28.987	570,840	$ 29.387
$39.063 75.250	595,028	6.91	$ 52.902	457,315	$ 53.591
	4,293,643	7.97	$ 14.749	1,821,002	$ 26.327

Restricted Stock Units

In March 2004, the Company granted a total of 154,655 restricted stock units to employees. Subject to each grantee s continued employment, shares underlying restricted stock unit grants vest in four semi-annual installments. The Company issued 53,788 shares for restricted stock units that vested in 2004. 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 $227,000 related to restricted stock units in the year ended December 31, 2004. As of December 31, 2004, 84,238 restricted stock units were outstanding.

Employee Stock Purchase Plan

The Company has reserved 570,500 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 90,757, 86,300 and 27,446 shares under the Purchase Plan during the years ended December 31, 2004, 2003 and 2002, respectively. At December 31, 2004, 268,761 shares were available for issuance. The weighted average fair value per share of the rights granted during the years ended December 31, 2004, 2003 and 2002 using the Black-Scholes model was $2.286, $3.004 and $19.357, respectively.

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 $2,861,000 associated with this restructuring. Restructuring costs primarily included severance benefits to employees terminated as a result of the restructuring. As of December 31, 2004, the accrual for restructuring was $692,000, related to severance benefits payable in installments until May 2006. The Company does not expect to record further costs related to this restructuring.

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:

	December 31, 2004	**2003**
	(in thousands)	
Net operating loss carryforward	$ 103,400	$ 100,100
Research and development credit carryforward	23,300	20,400
Deferred revenue	5,400	200
Capitalized research and development	5,200	5,300
Certain expenses not currently deductible for tax purposes	2,900	3,200
Accrued liabilities	800	1,200
Other	2,700	1,900
Gross deferred tax assets	143,700	132,300
Valuation allowance	(143,700)	(132,300)
Net deferred tax assets	$	$

The valuation allowance increased by $11,400,000 and $29,200,000 for the years ended December 31, 2004 and 2003, respectively. The increase is primarily attributable to the increase in the net operating loss and tax credit carryforwards. The Company believes that, based on a number of factors, the available objective evidence creates sufficient uncertainty regarding the realizability of the deferred tax assets such that a full valuation allowance has been recorded. These factors include the Company s history of net losses since its inception, the need for regulatory approval of the Company s products prior to commercialization, expected near-term future losses and the absence of taxable income in prior carryback

years. The valuation allowance at December 31, 2004, includes $2,900,000 related to deferred tax assets arising from tax benefits associated with stock option plans. This benefit, when realized, will be recorded as an increase in stockholders equity rather than as a reduction in the income tax provision.

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

At December 31, 2004, the Company had net operating loss carryforwards of approximately $275,600,000 for federal and $161,500,000 for state income tax purposes. The Company also had research and development tax credit carryforwards of approximately $15,900,000 for federal income tax purposes and approximately $11,200,000 for state income tax purposes at December 31, 2004. The federal net operating loss and tax credit carryforwards expire between the years 2007 and 2024. The state net operating loss carryforwards expire between the years 2005 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.

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, 2004, 2003 and 2002.

10. Quarterly Financial Information (Unaudited)

	Three Months Ended March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004
	(In thousands, except per share data)			
Revenue:				
Milestone and development funding, related party	$ 192	$ 301	$ 108	$ 150
Development funding, other	89	164	1,107	2,076
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)

	Three Months Ended			
	March 31, 2003	June 30, 2003	September 30, 2003	December 31, 2003
	(In thousands, except per share data)			
Revenue:				
Milestone and development funding, related party	$	$	$	$ 398
Development funding, other	169	113	257	85
Government grants and cooperative agreements	1,080	1,882	2,587	3,042
Product sales	20	8	24	
Total revenue	1,269	2,003	2,868	3,525
Operating expenses:				
Research and development	14,695	14,752	13,400	9,637
General and administrative	2,695	2,823	2,587	2,911
Total operating expenses	17,390	17,575	15,987	12,548
Loss from operations	(16,121)	(15,572)	(13,119)	(9,023)
Net interest expense	(1,038)	(1,200)	(1,089)	(1,105)
Net loss	$ (17,159)	$ (16,772)	$ (14,208)	$ (10,128)
Net loss per share basic and diluted	$ (1.07)	$ (0.97)	$ (0.64)	$ (0.46)

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 29th day of April 2005.

CERUS CORPORATION
By: /s/ CLAES GLASSELL
Claes Glassell
President and Chief Executive Officer

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)*	April 29, 2005
/s/ WILLIAM J. DAWSON William J. Dawson	Chief Financial Officer and Vice President, Finance *(Principal Financial and Accounting Officer)*	April 29, 2005
* B. J. Cassin	Chairman of the Board	April 29, 2005
* Timothy B. Anderson	Director	April 29, 2005
* Laurence M. Corash, M.D.	Director	April 29, 2005
* Bruce C. Cozadd	Director	April 29, 2005
* William R. Rohn	Director	April 29, 2005

* By: /s/ CLAES GLASSELL
Claes Glassell,
Attorney-in-fact

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.

* Compensatory Plan.