

Cerus Corporation

2007 Annual Report



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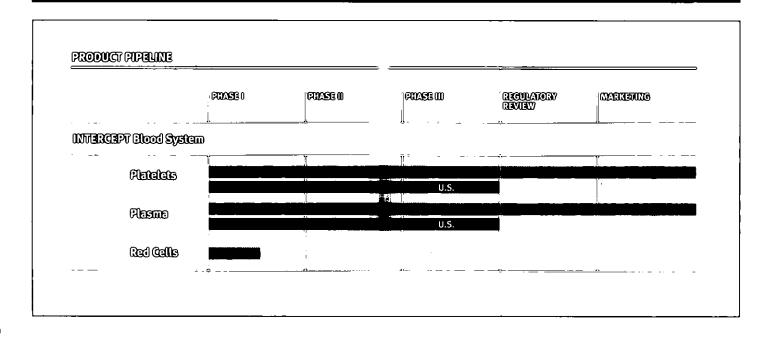
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Washington, DC 2000 MSON REUTERS

safety in numbers

Every 2 seconds, someone in the world needs a blood transfusion.  $\equiv$  More than half of us will receive a blood transfusion at some point during our lifetime.  $\equiv$  1 in 7 people admitted to a hospital need blood.  $\equiv$  More than 81 million units of blood are collected globally every year.  $\equiv$  There are 7.5 million platelet and plasma transfusions each year in Europe alone.  $\equiv$  The addressable market in the United States for INTERCEPT-treated platelets and plasma is approximately \$400 million.  $\equiv$  1 pint of blood can save up to 3 lives.  $\equiv$  Over 100,000 INTERCEPT platelet kits have been shipped to customers in 20 countries.  $\equiv$  There has been at least 1 new emerging pathogen each year for the past 40 years.  $\equiv$  Cerus has over 50 customers throughout Europe, Russia and the Middle East with 34 new customer contracts signed in 2007.  $\equiv$  Distributors in 8 countries: Spain, Portugal, Turkey, Greece, Kuwait, Russia, Poland and Italy.

Over 100,000 INTERCEPT platelet and plasma system kits have been shipped to more than 50 customers in 20 countries.

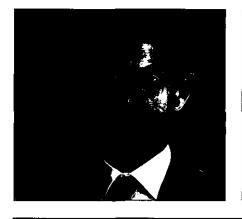


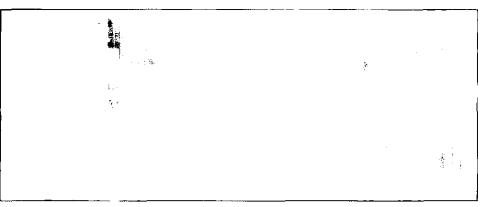
safety in numbers

# When it comes to blood safety, the most important number at Cerus is 100%.

That's because we are 100% committed to developing and commercializing biomedical products that enhance the safety and availability of donated blood. Dr. Larry Corash, our Chief Medical Officer, co-founded Cerus after witnessing the devastating effects that HIV/AIDS wreaked on his patients and recognizing the threat that emerging pathogens posed to the safety of the blood supply. With the commercialization of our pathogen inactivation technology, the INTERCEPT Blood System for platelets and plasma, our products are enabling a new blood safety paradigm.

Safety in numbers. That's the Cerus commitment, 100%.





## Dear Shareholder:

When it comes to blood safety, it's all about numbers – numbers that relate to the prevalence of blood-borne pathogens, testing windows, limits of detection, the risk of contamination and the amount of blood available to patients who need it. In recent years, these numbers have made it clear that health care systems around the world face new challenges in ensuring the safety and availability of donated blood. New pathogens continue to emerge, more stringent screening criteria reduce the pool of potential donors, and each new test adds to the cost of processing life-saving blood. That's why everyone at Cerus is 100% committed to making our INTERCEPT products number one in pathogen inactivation.

Our 2007 numbers make it clear that we are making excellent progress toward that goal. We have now entered into distributor relationships in eight countries and in 2007 signed 34 new customer contracts for INTERCEPT products. Today, we have 35 employees selling and supporting INTERCEPT products under the Cerus brand to over 50 customers throughout Europe, Russia and the Middle East. As a result of our success in commercializing INTERCEPT, our 2007 product sales revenue nearly tripled compared with 2006.

With over 100,000 INTERCEPT platelet kits shipped to date, our clinical-use numbers are helping to drive our commercialization efforts. Customers using the INTERCEPT blood system for platelets report a significant reduction in transfusion-related adverse events. Commercial data indicate that the use of INTERCEPT-treated platelets has reduced the number of adverse events on average by half. This decrease in adverse events can result in healthcare savings by reducing hospital stays, complications and antibiotic and steroid use. Perhaps most importantly, transfusing INTERCEPT-treated platelets may result in better patient outcomes compared with conventionally prepared platelets.

In 2007, newly generated data highlighted an additional product benefit of the INTERCEPT platelet system. INTERCEPT-treated platelets can be stored for up to seven days according to an allowed label claim in most European markets, compared to a five day shelf life for conventionally prepared platelets. This two day difference in shelf life can allow customers to reduce waste and improve inventory control. This stands in stark contrast to the results of the PASSPORT study, which was conducted in the United States by other commercial groups in order to assess the safety of conventional platelets tested for bacterial contamination and stored for seven days.

The PASSPORT study was halted when levels of bacterial contamination were found to be five times higher than the FDA-accepted minimum. By inference, the PASSPORT study revealed that roughly 1 in every 330 patients receiving platelet transfusions is at risk of a bacterial infection even after donations are initially tested for presence of bacteria, an unacceptably high rate of contamination. Given that bacteria know no geographic boundaries, we believe that the results of the PASSPORT study have important ramifications for the safety of the world's blood supply and the commercial opportunity for INTERCEPT in U.S. and foreign markets. INTERCEPT's demonstrated ability to inactivate bacteria provides customers with important clinical and economic benefits.

Combined, these clinical, commercial and epidemiologic numbers position us for growth in 2008 and beyond. Based on a growing body of data from the use of INTERCEPT in hospital settings, we are well positioned to articulate the safety, patient outcomes and economic benefits that the system offers. Moreover, both the international Consensus Conference on pathogen inactivation held in Toronto, Canada and the U.S. Department of Health and Human Services' Advisory Committee on Blood Safety and Availability have recommended broad implementation of pathogen inactivation.

While these data should help us to attract new customers in countries that recognize the CE mark for the INTERCEPT platelet and plasma systems, they also have helped to potentially provide a more clear and rapid path to commercialization in the United States. In a meeting with the FDA's Office of Blood Research and Review in January 2008, we were told that commercial data to be gathered from use of INTERCEPT-treated platelets in Europe, in combination with our existing Phase III trial data, could provide a basis for approval of the system in the United States. This change from a prior requirement for a new Phase III trial makes FDA approval a more immediate and less expensive priority than we had previously anticipated. While we still need to finalize a regulatory plan and collect data that the FDA would find acceptable, we are encouraged by the agency's change in approach. We believe the U.S. market opportunity for the INTERCEPT platelet and plasma systems is approximately \$400 million, and we are committed to establishing the INTERCEPT brand as the first and best in class for pathogen inactivation of blood components.

As part of that commitment, we spun off our immunotherapy business in November 2007 to a newly formed company, Anza Therapeutics, which was funded by leading venture capital firms Kleiner Perkins, Sofinnova and Versant Ventures. This strategic transaction was undertaken in order to focus our resources solely on commercializing the INTERCEPT Blood System.

As we move through 2008 and beyond, our three priorities are to continue expanding the commercialization of the INTERCEPT platelet and plasma systems in Europe and the Middle East, clarifying and executing a regulatory strategy for INTERCEPT in the United States and advancing the INTERCEPT red blood cell system, currently in early-stage clinical trials, through later-stage clinical development and ultimate commercialization.

We are 100% committed to blood safety. With our demonstrated success commercializing the INTERCEPT platelet and plasma systems in 2007, that's a number that should make patients and our shareholders feel safer.

Sincerely,

Claes Glassell

President and Chief Executive Officer

April 14, 2008



More than 4.5 million patients need blood transfusions each year in the U.S. and Canada.

4.5



There has been at least one new emerging pathogen each year for the past 40 years.



300,000 PEOPLE IN THE UNITED STATES ALONE CONTRACTED HEPATITIS C THROUGH BLOOD TRANSFUSIONS OR BLOOD PRODUCTS BEFORE A COMMERCIAL TEST FOR HCV BECAME AVAILABLE.

Blood-borne pathogens pose two great threats to the blood supply. First, potential transmission of potentially life-threatening pathogens, such as hepatitis B, hepatitis C and HIV, compromises safety by creating a risk for individuals who receive blood in transfusions. Second, widespread outbreaks can shut down blood collection and distribution, thus reducing the availability of blood for patients who need it. Cerus' blood safety solutions address both of these critical concerns.

Cerus is enabling a new and enhanced approach to blood safety, one designed to address the needs of the blood transfusion community around the world. Current blood safety paradigms call for screening of donors to eliminate those with increased risk for harboring or transmitting blood-borne infections and testing donated blood for the presence of pathogens. While these approaches have helped to improve the safety of the blood supply, they have limitations. Screening depends on the accuracy of the information provided by the donor, which cannot always be independently verified. This leaves open the risk that infected individuals will donate blood. Additionally, as screening criteria grow ever more stringent, the pool of potential donors is shrinking. A smaller donor pool makes it more difficult to meet the demand for blood components, creating a significant risk to the health of patients who need but cannot obtain them. And demand for blood components is rising, as people live longer and may undergo more surgical interventions.

Testing is only as effective as the limits of detection for specific pathogens. Below or beyond these limits, it is possible that pathogens may be present but not detected. This creates a risk that contaminated blood will enter our blood supply. Additionally, there is no single test that can be used for all pathogens, and the use of multiple tests adds to the cost of processing donated blood.

Perhaps the most serious limitation of current screening and testing methods is that this approach can only be applied to known pathogens. And even as new threats are detected, there is a lag period until reliable screening and testing procedures can be developed. What about pathogens we cannot test for or those we are not even aware? Cerus' pathogen inactivation technology can be an answer to this challenging and critical question about blood safety.

Cerus' INTERCEPT Blood System is a new and important layer of protection for blood components used for transfusion. The INTERCEPT system is designed to prevent replication of a broad spectrum of viruses, bacteria and parasites — both known and unknown. INTERCEPT also inactivates white blood cells, which can lead to a range of adverse events, including a potentially lifethreatening adverse event known as graft versus host disease. The scientific foundation underpinning INTERCEPT is simple yet elegant: all of these potential contaminants of donated blood contain functional DNA or RNA, while platelets, plasma and red blood cells do not. Thus, inhibiting the replication of DNA and RNA on a nonspecific basis renders viruses, bacteria, parasites and harmful white blood cells incapable of propagating, while allowing blood components to function normally.

At Cerus, we believe that the safety and availability of today's blood supply is too critical to depend on knowledge that we may not learn until tomorrow. That's why we're 100% committed to making INTERCEPT number one in pathogen inactivation.

France. Germany. Russia. Poland. Turkey. Greece. Spain. Belgium. Kuwait. Sweden. Different countries. Different climates. Different customs. What do they have in common? All of them have INTERCEPT customers. In a world where threats to the blood supply encounter fewer geographic boundaries, INTERCEPT has global potential and local impact. INTERCEPT platelets and plasma offer customers enhanced safety, improved economics and better patient outcomes. That's an equation for success.

2007 was the first full year in which Cerus had sole marketing and commercialization responsibility for the INTERCEPT product line, and our achievements in the year provide a solid foundation on which to expand our market penetration.

With full rights to the product, we implemented plans to enhance the product positioning for the INTERCEPT platelet and plasma systems in the numerous territories that recognize these systems' CE marks. This strategy included emphasizing the value proposition and commercial competitiveness of the INTERCEPT Blood System and highlighting INTERCEPT's compatibility with a variety of blood collection platforms, as well as its utility with both pooled blood and individual collections.

We believe that INTERCEPT offers a number of benefits over conventional blood safety measures. For platelets, INTERCEPT may obviate the need for bacterial and CMV tests as well as gamma irradiation, and provides multiple processing advantages that decrease cost and improve inventory management. Combined, these benefits can serve to offset much of the cost of the INTERCEPT Blood System. Moreover, INTERCEPT platelets may provide economic benefits to healthcare systems and payors by reducing transfusion-related adverse events, potentially eliminating the need to add new tests for emerging pathogens and expanding the donor pool. The INTERCEPT plasma system offers benefits with respect to cost, ease of use and efficacy compared with quarantine or other pathogen inactivation methods used on plasma for transfusion.

The combined potential market for the INTERCEPT platelet and plasma systems in Europe alone is \$425 million, and approximates \$500 million together with other countries we are targeting that

also recognize the CE mark. We are committed to penetrating the European and Middle Eastern markets to the fullest. Key to our market expansion is our ability to work with customers and national policy makers to expedite adoption of our INTERCEPT products. In 2007 we opened new markets in countries throughout Europe, Eastern Europe and the Middle East. In several countries with expanding economies and improving medical care, health officials are bypassing traditional screening and testing paradigms in favor of pathogen inactivation with INTERCEPT. We signed 34 new customer agreements in 2007, and we expect that continued implementation of INTERCEPT by our geographically diverse and growing customer base will further enhance the brand's acceptance and market opportunity around the globe.

As part of our commercialization strategy, we recently welcomed Carol Moore as Vice President, Regulatory Affairs and Quality. In this capacity, Carol will coordinate our global regulatory strategy. This includes a continuation of our work with the FDA to establish a clear path for commercializing the INTERCEPT platelet and plasma systems in the U.S. market, which has an estimated potential of \$400 million.

With 35 employees and multiple distributors focused on selling INTERCEPT products to over 50 customers in Europe, Russia and the Middle East, our sales revenue for 2007 nearly tripled compared with the prior year. So, what do these numbers add up to? Success in 2007 and multiple opportunities for continued achievement in 2008 and beyond.



OVER 100,000 INTERCEPT PLATELET KITS HAVE BEEN SHIPPED TO CUSTOMERS.

Distributor relationships in 8 countries: Spain, Portugal, Turkey, Creece, Kuwait, Russia, Poland and Italy.

50

50 customers throughout Europe, Russia and the Midelo task

4 fold increase in West Nile Virus infections in the United States over the past year.

300 people infected with Chikungunya virus, a mosquito-borne emerging pathogen, in a 2007 outbreak in Italy.

300



Some 6,000 cases of Dengue fever in Puerto Rico. Over 250,000 cases of Chikungunya virus in La Réunion, with a significant number of documented cases in India and now Italy. Blood-borne pathogens don't need visas or passports to enter new countries. That's why Cerus is dedicated to expanding INTERCEPT's global reach.

The global market opportunity for pathogen inactivation of platelets, plasma and red blood cells for transfusion is estimated to be in excess of \$5.4 billion. While we believe that the current value proposition offered by the INTERCEPT platelet and plasma systems are powerful drivers for adoption, our growth opportunities are enhanced by several external factors.

Dengue fever and Chikungunya virus are just two examples of blood-borne diseases that have moved from tropical environments to the United States and Europe. Chagas disease and West Nile Virus are on the rise in the United States. The Chikungunya outbreak on the island of La Réunion briefly shut down the blood supply, when significant numbers of residents contracted the virus and blood could no longer be sourced safely from local donors. Rapid implementation of the INTERCEPT platelet system facilitated the resumption of blood collection and platelet supply, easing the crisis for those patients needing platelet transfusions.

The La Réunion outbreak demonstrates just how vulnerable the blood supply can be to an emerging pathogen, and such outbreaks are likely to grow more common. The World Health Organization reported that, on average, one new pathogen has emerged each year for the past 40 years, and predicts that this trend is quite likely to continue. Pathogenic outbreaks are expected to occur with greater frequency in previously unaffected areas as global travel expands. Long development and approval periods for new tests, and a reluctance on the part of diagnostics manufacturers to develop incremental new tests for every emerging pathogen suggests that the current testing paradigm cannot meet the challenge posed by emerging pathogens.

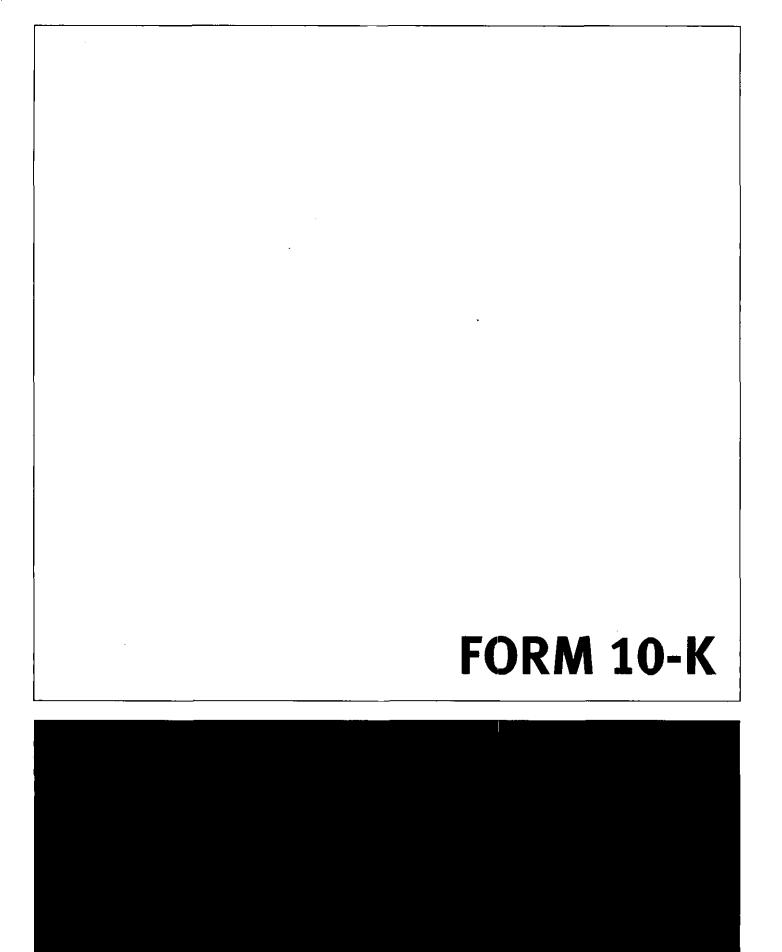
Clearly, 21<sup>st</sup>-century challenges to the safety of the blood supply require innovative solutions. Blood safety experts at both the 2007 international Consensus Conference on pathogen inactivation in

Toronto, Canada and a January 2008 U.S. Advisory Committee on Blood Safety and Availability meeting put forth the same recommendation: pathogen inactivation should be adopted now. This recommendation was based on findings that existing viral and bacterial testing strategies are inadequate and the blood supply is vulnerable to emerging pathogens.

We believe that these recommendations, combined with clinical experience from the more than 100,000 INTERCEPT-treated platelet units transfused in hospital settings, provide a solid foundation on which to build and expand the INTERCEPT franchise. Near-term growth opportunities include reaching additional customers in territories that recognize the CE mark for the INTERCEPT platelet and plasma systems. Longer term, we are focused on gaining approval of the INTERCEPT platelet and plasma systems in the United States and commercializing the INTERCEPT red blood cell system.

The global market for INTERCEPT-treated red blood cells is estimated to be nearly \$4 billion. A recently completed Phase I trial highlighted the need to further optimize the system to simultaneously reduce antibody reactivity and maintain the life span of stored red blood cells. We expect to initiate another Phase I clinical trial before the end of 2008 with a system we believe addresses both of these issues, and are committed to expanding the INTERCEPT franchise into this large and medically important market.

Inadequate testing, emerging pathogens, demand for blood components that threatens to outpace supply. These are the challenges to blood safety in the 21<sup>st</sup> century. INTERCEPT offers a straightforward solution to this complicated equation.



### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### **FORM 10-K**

TORM				
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934				
For the fiscal year ende OR				
TRANSITION REPORT PURSUANT TO SEC' SECURITIES EXCHANGE ACT OF 1934				
For the transition period from	n to			
Commission file n				
CERUS CORPORATION (Exact name of registrant as specified in its charter)				
Delaware	68-0262011			
(State or other jurisdiction of	(I.R.S. Employer			
incorporation or organization)	Identification No.)			
2411 Stanwell Dr.	0.4530			
Concord, California (Address of principal executive offices)	94520 (Zip Code)			
(925) 288				
(Registrant's telephone num				
Securities registered pursuant to Section 12(b) of the Act: NASDAQ Global Market				
Securities registered pursuant				
Common Stock, par va (Title of				
Indicate by check mark if the registrant is a well-known seaso	ned issuer, as defined in Rule 405 of the Securities Act.			
Yes No X				
Indicate by check mark if the registrant is not required to file registrant is not required to file results a value of the registrant is not required to file required to file registrant is n				
Indicate by check mark whether the registrant: (1) has filed all Securities Exchange Act of 1934 during the preceding 12 months (exchange such reports), and (2) has been subject to such filing requirements in	or for such shorter period that the registrant was required to file			
Indicate by check mark if disclosure of delinquent filers pursu	ant to Item 405 of Regulation S-K, (§229.405 of this chapter) is			
not contained herein, and will not be contained, to the best of regist incorporated by reference in Part III of this Form 10-K or any amer	rant's knowledge, in definitive proxy or information statements			
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule				
12b-2 of the Exchange Act. (Check one):	A1			
Large accelerated filer	Accelerated filer ⊠ ting company) Smaller reporting company □			
Non-accelerated filer [ ] (Do not check if a smaller report Indicate by check mark whether the registrant is a shell compared to the compared				
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 Global Market, was \$179.6 million.(1)				
As of February 8, 2008, there were 32.2 million shares of the	registrant's common stock outstanding.			
DOCUMENTS INCORPOR				
Portions of the registrant's definitive proxy statement in connection with the registrant's 2007 annual meeting of stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than April 30, 2008, are incorporated by reference into Part III of this annual report on Form 10-K.				

(1) Based on a closing sale price of \$6.76 per share on June 29, 2007. Excludes 5.3 million shares of the registrant's common stock held by executive officers, directors and affiliates at June 29, 2007.

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#### PART I

This report contains forward-looking statements that involve risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "expect," "plan" and similar expressions are intended to identify such forward-looking statements. There can be no assurance that these statements will prove to be correct. Certain important factors could cause actual results to differ materially from those discussed in such statements, including whether our preclinical and clinical data or data from commercial use will be considered sufficient by regulatory authorities to grant marketing approval, market acceptance of our products, reimbursement, development and testing of additional configurations of our products, regulation by domestic and foreign regulatory authorities, a transition away from a reliance on Baxter and Fenwal for sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Fenwal and third parties to manufacture certain components of the INTERCEPT Blood System, our successful completion of our product components' commercial design, our reliance on our relationship with BioOne Corporation, more effective product offerings by, or clinical setbacks of, our competitors, product liability, potential for financial return from the spin-off of our immunotherapy business, our use of hazardous materials in the development of our products, business interruption due to earthquake, our limited operating history and expectation of continuing losses, the need for additional financing, protection of our intellectual property rights, volatility in our stock price, legal proceedings, on-going compliance with the requirements of the Sarbanes-Oxley Act of 2002 and other factors discussed below and under the caption "Risk Factors," in Item 1A and in our other documents filed with the Securities and Exchange Commission. We undertake no obligation to update any of the forward-looking statements contained herein to reflect any future events or developments.

Cerus, INTERCEPT and INTERCEPT Blood System are United States registered trademarks of Cerus Corporation.

#### Item 1. Business

#### Overview

We are a biomedical products company focused on commercializing the INTERCEPT Blood System to enhance blood safety. The INTERCEPT system is designed to inactivate blood-borne pathogens in donated blood components intended for transfusion. The company currently markets the INTERCEPT system for both platelets and plasma in Europe and the Middle East. We are also pursuing regulatory approvals in the United States and other countries. The INTERCEPT red blood cell system is currently in clinical development.

We have worldwide commercialization rights for the INTERCEPT Blood System for platelets, plasma and red blood cells, excluding certain countries in Asia where we have licensed commercialization rights to the platelet and plasma systems to BioOne Corporation, or BioOne. We previously collaborated with subsidiaries of Baxter International Inc., or Baxter, in the development and commercialization of the INTERCEPT Blood System. In February 2005 and February 2006, we announced agreements with Baxter that resulted in our acquisition of all commercialization rights to the INTERCEPT Blood System that have not been licensed to BioOne. The INTERCEPT platelet and plasma systems have both received CE mark approval and are being marketed for commercial sale directly or through distributors in a number of countries in Europe and the Middle East. Certain European countries require additional approvals of INTERCEPT-treated blood products. Such additional approvals have been obtained for the platelet and plasma systems in France and for INTERCEPT-treated platelets at one blood center in Germany. We submitted filings with SwissMedic in 2007 for approval to market the platelet and plasma systems in Switzerland. We have as priorities, the commercialization of the INTERCEPT Blood System for platelets and plasma in Europe and the United States, and the continued development of the INTERCEPT red blood cell system in pursuit of regulatory approval activities in the United States.

In November 2007, we announced that we had sold certain assets that made up our immunotherapy business, including our Listaria and KBMA platform technologies, to a newly formed independent company, Anza Therapeutics, Inc. The immunotherapy business is accounted for as a discontinued operation.

We were incorporated in California in 1991 and reincorporated in Delaware in 1996. Information regarding our revenue, net income or losses, and total assets for the last three fiscal years can be found in the financial statements and related notes found elsewhere in this Annual Report. Our wholly-owned subsidiary, Cerus Europe B.V. was formed in the Netherlands in 2006.

#### **Product Development**

We have incurred total research and development expenses from continuing operations of \$15.0 million, \$16.0 million and \$10.7 million for the years ended December 31, 2007, 2006 and 2005, respectively. The following table identifies our products and product development programs and their current status:

Product or Product Under Development	Development Status	Commercial Rights
INTERCEPT Blood System—Platelets	Europe: Commercialized in certain countries U.S.: Phase III clinical trial completed; supplemental data from commercial use required	Worldwide, other than rights granted to BioOne in certain Asian countries
INTERCEPT Blood System—Plasma	Europe: Commercialized in certain countries U.S.: Phase III clinical trials completed	Worldwide, other than rights granted to BioOne in certain Asian countries
INTERCEPT Blood System—Red Blood Cells	Planning Phase I clinical trial expected to begin in second half of 2008	Worldwide

#### Background

The INTERCEPT Blood System is designed to broadly target and inactivate blood-borne pathogens, such as viruses (HIV, West Nile, SARS, and hepatitis B and C, for example), bacteria and parasites, as well as potentially harmful white blood cells, while preserving the therapeutic properties of platelet, plasma and red blood cell transfusion products. The INTERCEPT Blood System inactivates a broad array of pathogens and has the potential to reduce the risk of transfusion related transmission of pathogens for which testing is not completely effective or is not currently performed. We believe that the INTERCEPT Blood System also has the potential to inactivate most new pathogens before they are identified and before tests are developed and adopted to detect their presence in donated blood. In addition, data from commercial use suggests that the INTERCEPT platelet system substantially reduces the rate of transfusion related adverse events as compared to the incidence of such events prior to adoption. The INTERCEPT Blood System is based on our proprietary technology for controlling biological replication.

We have worldwide commercialization rights for the INTERCEPT Blood System, excluding certain countries in Asia. Baxter and we have licensed to BioOne commercialization rights to the INTERCEPT Blood System for platelets and plasma in Japan, China, Taiwan, South Korea, Thailand, Vietnam, and Singapore.

#### Products, Product Candidates and Development Activities

INTERCEPT Blood System for Platelets

The INTERCEPT Blood System for platelets, or platelet system, is designed to inactivate blood-borne pathogens in donated platelets for transfusion. The platelet system has received CE mark approval in Europe and is being marketed and sold in several countries in Europe, Asia and the Middle East. Certain European countries require additional approvals of INTERCEPT-treated blood products. Such additional approvals have been obtained for the platelet system in France and for INTERCEPT-treated platelets at several blood centers in

Germany. We have filed an application for marketing approval to SwissMedic, the regulatory body in Switzerland, which must approve our filing before we will able to sell the platelet system there. The extent of the validation studies varies by country. Further clinical studies, ranging from small-scale experience studies to larger randomized trials, will be conducted in some regions and countries. These studies may be conducted to gain broader market acceptance, expand product labeling or provide data to support applications for regulatory and/or reimbursement approval. In France, the platelet system has been approved for use by blood centers in treating platelets, and in June 2007, we signed an initial supply contract for purchase of our platelet and plasma systems with Etablissement Français du Sang, or EFS, the French national blood service, pursuant to a public tender process. However, widespread adoption of the platelet system throughout France has been delayed pending budget authorization from the French Ministry of Health to support a larger national contract with the EFS.

We completed a Phase III clinical trial of the platelet system in the United States in March 2001 and have submitted data from this trial, along with several other modules of our pre-market approval application, to the United States Food and Drug Administration, or FDA. Based on discussions with the FDA, an independent expert physician panel performed an additional analysis of some of the clinical trial data, which was collected by an independent contract research organization, to determine if apparent differences between treatment groups in the category of pulmonary adverse events reported in the study were attributable to inconsistent event reporting. The assessments of primary patient records on a blinded basis by the independent expert physician panel found no statistically significant differences in clinically significant pulmonary adverse events between test and control groups. These assessments differed from adverse events drawn from the case report forms from the Phase III clinical trial, which showed statistically significant differences in specific pulmonary events. Furthermore, this assessment supported our interpretation that the imbalance observed based on the case report forms was due to reporting differences among the clinical sites. Together with Baxter, we submitted in 2005 a final report of the analysis to the FDA for review. The final report included conclusions from the expert physician panel. We have had several interactions with the FDA subsequent to the final report submission and understand that the FDA may consider non-randomized data derived from commercial use of the platelet system in Europe in conjunction with previously completed Phase III data from randomized clinical trials conducted in the United States. Such data from commercial use will need to be in a form and substance deemed acceptable to the FDA. There is no assurance that we will be able to reach agreement with the FDA on the data to be collected, that we will be able to collect such data, or that the FDA will find such data from commercial use adequate to answer questions that the FDA has concerning the safety and efficacy of the platelet system. As a result, the FDA may still require a significantly larger randomized, blinded clinical trial than we and Baxter completed in 2001 before a product license application can be finalized and the platelet system considered for approval in the United States.

Information regarding our revenues from the platelet system for the years ended December 31, 2007, 2006, and 2005 can be found in "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operation", and "Item 15(a)—Consolidated Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

#### INTERCEPT Blood System for Plasma

The INTERCEPT Blood System for plasma, or plasma system, is designed to inactivate blood-borne pathogens in donated plasma for transfusion. We completed the last of three planned Phase III clinical trials of the plasma system in 2004, and the primary and secondary efficacy endpoints of the trials for therapeutic plasma exchange were met. The study showed no clinically and statistically significant differences in overall adverse events between the treatment group and the control group. A final Phase III report was submitted to the FDA in 2005. Based on the results of the Phase III clinical trials, we received CE mark approval for the plasma system in November 2006 and have prioritized the commercial launch of the plasma system in Europe ahead of further regulatory efforts relating to the plasma system in the United States. We obtained French in-country approval of the plasma system in early 2007. In June 2007, we signed an initial supply contract with the EFS pursuant to a public tender process, which also applies to the plasma system. However, broader adoption of the plasma system

throughout France has been delayed pending budget authorization from the French Ministry of Health to support a larger national contract with the EFS. Pathogen inactivated plasma is already reimbursed in many European countries, including France.

Information regarding our revenues from the plasma system for the years ended December 31, 2007, 2006, and 2005 can be found in "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operation," and "Item 15(a)—Consolidated Financial Statements and Supplementary Data" of this Annual Report on From 10-K."

#### INTERCEPT Blood System for Red Blood Cells

The INTERCEPT Blood System for red blood cells, or red blood cell system, is designed to inactivate blood-borne pathogens in donated red blood cells for transfusion. In September 2003, we terminated Phase III clinical trials of the red blood cell system due to the detection of antibody reactivity to INTERCEPT-treated red blood cells in one patient in the chronic arm of the trial. However, there were no medical sequelae associated with INTERCEPT-treated red blood cells evident in this trial. The antibody cleared and the patient had no adverse health consequences. After unblinding the data from the Phase III trial, we found that we had met the primary end-point in the acute arm of the trial. We evaluated the antibodies detected in the trial and have developed process changes that may greatly diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. We announced several findings related to these evaluations and developments in late 2004 and 2005 at several scientific and trade association meetings. Based on these findings and other preclinical work we have conducted, we re-entered Phase I clinical trials for the red blood cell system in the United States in the second half 2006 with our modified process, which were completed in mid-2007. While we determined that the modifications we made in this Phase I trial appeared to be safe, they resulted in irreversible deyhydration and unacceptably short lifespan of the treated red blood cells. We are currently engaged in a series of in vitro and in vivo tests with further modifications to the red blood cell system to correct the shorter lifespan issue and plan to enter another Phase I clinical trial in the second half of 2008. We expect to spend approximately two years developing and implementing commercial product and system design changes to the original red blood cell system prior to entering Phase III clinical trials.

#### Collaborations

#### Baxter

We collaborated with Baxter on the development and commercialization of the INTERCEPT Blood System commencing in 1993. Effective February 1, 2006, we entered into a restructuring of our agreements with Baxter pursuant to which we obtained exclusive worldwide commercialization rights to market, distribute and sell the platelet and plasma systems, excluding certain Asian countries where the commercialization rights had been licensed to BioOne. We also obtained worldwide commercialization rights to market the red blood cell system from Baxter in February 2005. In connection with the transfer of commercialization rights to us, Baxter agreed to supply, at our expense, certain transition services, including regulatory, technical and related administrative support through December 31, 2006. We agreed to purchase UVA illumination devices from Baxter in inventory in February 2006 and, INTERCEPT Blood System disposable kit finished from Baxter's inventory for the platelet and plasma systems. Baxter agreed to manufacture systems and components for the platelet and plasma systems on a cost-plus basis through December 31, 2008, and components through December 31, 2009, subject to extension under certain specified conditions. Baxter also agreed to supply only very limited types of components for the prototype of the red blood cell system. We agreed to pay Baxter royalties on future INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system, 3% for the plasma system and 5% for the red blood cell system. As a result of the 2006 restructuring agreement, we recognized gains and deferred gains in excess of \$6.5 million in 2006 and \$0.6 million in remaining deferred gains in 2007 as the services were completed by the vendors. In March 2007, Baxter sold its Transfusion Therapies business, the unit of Baxter that has performed many of the manufacturing and supply chain activities related to our relationship with Baxter, to a new company, Fenwal Inc., or Fenwal.

We were informed by Baxter that Fenwal has assumed Baxter's obligations to us under the manufacturing agreement and we are obligated to pay royalties on INTERCEPT Blood System product sales to Fenwal, rather than to Baxter.

#### BioOne

In June 2004, we entered into a definitive agreement with Baxter and BioOne for commercialization of our platelet system in specified parts of Asia. Under the terms of the 2004 agreement, BioOne is responsible, at its expense, for seeking regulatory approvals for the platelet system in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore in exchange for exclusive marketing and distribution rights in each of those countries. We have received a total of \$10.0 million in up-front payments under the terms of the 2004 agreement and will be eligible to receive contingent milestone payments for our sole account and royalties on future product sales, which will be shared equally by Fenwal, as the successor to Baxter's interests, and us.

In June 2005, we announced our entry into a definitive agreement with Baxter and BioOne for commercialization of our plasma system in specified parts of Asia. Under the terms of the 2005 agreement, BioOne is responsible, at its expense, for seeking regulatory approvals for the plasma system in Japan, China, Taiwan. South Korea, Thailand, Vietnam and Singapore in exchange for exclusive marketing and distribution rights in each of those countries. We understand that Baxter transferred its rights and obligations with regard to BioOne to Fenwal in March 2007. Prior to the year ended December 31, 2007, we received a total of \$9.5 million in cash and \$10.0 million in BioOne equity securities in connection with the 2005 agreement, and will be eligible to receive (i) contingent milestone payments, payable to us solely; and (ii) royalties on future product sales, which will be shared by Fenwal and us.

#### U.S. Armed Forces

In February 2001, we were awarded \$2.6 million under a cooperative agreement with the Army Medical Research Acquisition Activity division of the Department of Defense. In September 2002, May 2003, January 2004, August 2004, July 2006, September 2006, and January 2007 we were awarded additional funding of \$5.0 million, \$6.0 million, \$5.5 million, \$3.7 million, \$1.0 million, \$3.5 million, and \$3.0 million respectively, all of which was for the continued funding of projects to develop our pathogen inactivation technologies to improve the safety and availability of blood for medical transfusions. Under the terms of the agreements, we are conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites, that are of concern to the U.S. Armed Forces.

In November 2007, we announced that we had sold certain assets that made up our immunotherapy business, including our Listeria and KBMA platform technologies, to a newly-formed independent company, Anza Therapeutics, Inc. (or Anza), financed by venture capital firms, including Kleiner Perkins Caufield & Byers, Sofinnova Ventures and Versant Ventures. In exchange for our contribution of tangible and intangible assets to Anza, we received an equity interest of approximately 15.5% of Anza's fully diluted equity. In addition to equity, we are eligible to receive future cash milestone payments of up to in excess of \$90.0 million, as well as royalty payments, if vaccine candidates generated from the transferred assets are successfully developed and commercialized. Effective October 16, 2007, we ceased funding operations of the immunotherapy business that was transferred to Anza. The immunotherapy business is accounted for as a discontinued operation on our financial statements as of December 31, 2007. Accordingly, we have restated our statements of operations for the years ended December 31, 2006 and 2005 to reflect that accounting treatment.

#### Manufacturing and Supply

We have used, and intend to continue to use, third parties to manufacture and supply the devices, disposable kits and inactivation compounds that make up the INTERCEPT Blood System for use in clinical trials and for commercialization. We have no experience in manufacturing products for clinical or commercial purposes. We

are dependent on Fenwal for the manufacture of INTERCEPT Blood System components and on contract manufacturers for the production of inactivation compounds, compound absorption components of the disposable kits and UVA illumination devices used in the INTERCEPT Blood System.

Under our agreements with Fenwal, as the successor to Baxter's interests, we are responsible for developing and delivering our proprietary inactivation compounds and adsorption media to Fenwal for incorporation into the final system configuration. Fenwal is responsible for manufacturing or supplying the disposable kits for the platelet and plasma systems, such as blood storage containers and related tubing, as well as any device associated with the inactivation process on a cost-plus basis through 2008 and components through 2009, subject to extension under specified conditions.

We have contracted with one manufacturing facility for the synthesis of amotosalen, an inactivation compound used in our platelet and plasma systems. Under this contract, we are not subject to minimum annual purchase requirements. However, if specified quantities of amotosalen are not purchased in any year, we are required to pay a maintenance fee of up to \$50,000 for such year. We currently have a stock of the compound sufficient to support the anticipated commercial demand for the platelet and plasma systems in Europe.

We and our contract manufacturers purchase certain raw materials for our inactivation compounds, materials and parts associated with compound adsorption devices and UVA illumination devices from a limited number of suppliers, some of which may require minimum annual purchase amounts. While we believe that there are alternative sources of supply for such materials, parts and devices, establishing additional or replacement suppliers for any of the raw materials, parts and devices, 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 inactivation compounds or materials and parts used to manufacture our compound absorption devices and UVA illumination devices, if required, would limit our ability to supply these materials, parts or devices.

#### Marketing, Sales and Distribution

The market for the INTERCEPT Blood System is dominated by a small number of blood collection organizations in the United States, Western Europe and Japan, where various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood component supplies. The largest European markets for our products are in England, Germany and France. In England, decisions on product adoption are centralized in the National Blood Service. In Germany, decisions on product adoption are expected to be on a regional or blood center-by-blood center basis. While obtaining CE marks allows us to sell the platelet and plasma systems to blood centers in Germany, blood centers in Germany must still obtain both local manufacturing approval and national marketing authorization from the Paul Ehrlich Institute before being allowed to sell platelets and plasma units treated with the INTERCEPT Blood System to transfusing hospitals and physicians. To date, one blood center in Germany has received such requisite approvals and authorizations for the platelet system. In France, decisions on product adoption are expected to be on a region-by-region basis under national supply contracts negotiated with the EFS.

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. National reimbursement rates for platelet pathogen inactivation must be agreed upon between the French Ministry of Health and the EFS before we would expect broad commercial adoption of the platelet system in France. National reimbursement rates for pathogen inactivated plasma units have been set in France, but need to be extended to include the INTERCEPT Blood System before we would expect broad commercial adoption of the plasma system in France.

Prior to February 2006, Baxter had been responsible for the marketing, sales and distribution of the platelet system in the United States, Europe and other regions not covered by the agreements with BioOne. Baxter also

had been responsible for the marketing, sales and distribution of the plasma system following marketing approval in Europe and other countries, excluding North America, and the regions covered by the agreements with BioOne. As a consequence of the February 2006 agreement with Baxter, we have established a wholly-owned subsidiary, Cerus Europe B.V., headquartered in the Netherlands and are building our own independent marketing and sales organization based in Europe to market and sell the INTERCEPT Blood System in Europe and the Middle East. We also have a small scientific affairs group that supports the commercialization efforts.

#### Competition

We believe that the INTERCEPT Blood System has certain competitive advantages over competing blood-borne pathogen inactivation methods that are either on the market, or in development. The INTERCEPT Blood System is designed for use in blood centers on a distributed basis with single units of blood products, which allows for integration with current blood collection, processing and storage procedures. Competing products in development or currently on the market, such as solvent detergent-treated plasma, use centralized processing that takes blood products away from the blood center. One potential competitor has recently received a CE mark for a pathogen inactivation process for platelets. Other competitors are marketing pathogen inactivation products or systems for treating donated plasma in Europe. There are no known competitors in the clinical development stage for pathogen inactivation of red blood cells. In addition to direct competition from other pathogen inactivation methods, we encounter indirect competition from other approaches to blood safety, including methods of testing blood products for bacterial and viral pathogens. Further discussion of the major competitors to our blood product business can be found in the risk factor entitled "If our competitors develop and market products that are more effective than our products and product candidates, our commercial opportunity will be reduced or eliminated. If competitors encounter difficulties or failures in human clinical trials or in commercial settings, we may face additional clinical, regulatory, and commercial challenges."

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, the amount of demonstrated reduction in transfusion related adverse events subsequent to adopting pathogen inactivation technology, robustness of treated platelets, ease of use, the scope and enforceability of patent or other proprietary rights, product value, product supply and marketing and sales capability. In addition, the length of time required for products to be developed and to receive regulatory and, in some cases, reimbursement approval are also important competitive factors. We believe that the INTERCEPT Blood System will compete favorably with respect to these factors, although there can be no assurance that it will be able to do so. The medical device and 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, 2007, we owned approximately 30 issued or allowed United States patents and approximately 65 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2012 and 2018. In addition, we have pending United States patent applications and have filed corresponding patent applications under the Patent Cooperation Treaty. We have a license from Fenwal to United States and foreign patents relating to the INTERCEPT Blood System, which expire from 2010 to 2022. Proprietary rights relating to our planned and potential products will be protected from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. There can be no assurance that any patents owned by or licensed to us will afford protection against competitors or that any pending patent applications now or hereafter

filed by, or licensed to, us will result in patents being issued. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

#### Government Regulation

We and our products are comprehensively regulated in the United States by the FDA and, in some instances, by state and local governments, and by comparable governmental authorities in other countries.

Our European investigational plan has been based on the INTERCEPT Blood System being categorized as Class III drug/device combinations under the Medical Device Directives, or MDD, 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. The INTERCEPT Blood System for plasma received the CE mark in November 2006. A separate CE mark certification must be received for the red blood cell system to be sold in the European Union. Several European countries require additional in-country studies to support an approval to market the products in such countries.

The FDA regulates drugs, medical devices and biologics under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. These laws and implementing regulations govern, among other things, the development, testing, manufacturing, record keeping, storage, labeling, advertising, promotion and pre-market clearance or approval of products subject to regulation. The steps required before a medical device may be approved for marketing in the United States pursuant to a pre-market approval application, or PMA, include (i) preclinical laboratory and animal tests, (ii) submission to the FDA of an investigational device exemption 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 wellcontrolled human clinical trials to establish the product's safety and efficacy for its intended indications, (v) submission to the FDA of a PMA, and (vi) FDA review of the PMA 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 INTERCEPT systems for platelets, plasma and red blood cells. 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.

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

Before the FDA determines whether to approve our blood safety products, we expect our approval applications to be reviewed by the Blood Products Advisory Committee, or BPAC, an advisory committee convened by and reporting to the FDA. BPAC will make a recommendation to the FDA for, or against, approval. Before a medical device may be marketed in the United States, the FDA must approve a pre-market approval application for the product.

Baxter used a modular process for our PMA application for the platelet system in the United States, which we have followed since assuming responsibility for regulatory activities in the U.S. under terms of the February 2005 and 2006 agreements. The content, order and submission timing of the modules must be approved by the FDA, and a modular PMA application cannot be approved until all modules have been submitted to, reviewed by and accepted by the FDA.

In addition to the regulatory requirements applicable to the INTERCEPT Blood System, there are regulatory requirements applicable to our prospective customers, the blood centers that process and distribute blood and

blood products. Blood centers and others will likely be required to obtain approved license supplements from the FDA before using the INTERCEPT Blood System. There can be no assurance that any blood centers will be able to obtain the required licenses on a timely basis, or at all.

To support applications for regulatory approval to market the INTERCEPT Blood System, we conduct various types of studies, including toxicology studies to evaluate product safety, laboratory and animal studies to evaluate product effectiveness and human clinical trials to evaluate the safety, tolerability and effectiveness of treated blood components. We believe that, in deciding whether the INTERCEPT Blood System is safe and effective, 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 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 consist of studies that differ from typical Phase I, Phase II and Phase III clinical studies.

Many of the INTERCEPT Blood System preclinical and clinical studies have been conducted using prototype system disposables and devices. We have or 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 or foreign regulatory bodies 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 Fenwal. 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. If we elect to prioritize regulatory efforts in the United States, we may initially to seek FDA approval of the platelet system configured for Fenwal's apheresis collection equipment. If we determine that compatibility with other equipment is desirable, additional processing procedures and system configurations will need to be developed. We believe that the FDA will also require supplemental clinical data before approving our system for use with platelets collected using other equipment.

#### Health Care Reimbursement and Reform

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

Our ability to commercialize our products successfully will depend in part on the extent to which appropriate reimbursement levels for the cost of the products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly challenging the prices charged for pharmaceuticals, medical devices and services. The trend toward managed health care in the United States and other countries and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may all affect the prices for our products.

#### **Employees**

As of December 31, 2007, we had 111 employees, 49 of whom were engaged in research and development and 62 in selling, general, and administrative activities. Of the 62 employees engaged in selling, general, and administrative activities, 27 employees were employed by our European subsidiary, Cerus Europe B.V. None of our employees are covered by collective bargaining agreements, and we believe that our relationship with our employees is good.

#### **Available Information**

We maintain a website at www.cerus.com; however, information found on our website is not incorporated by reference into this report. We make available free of charge on or through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

#### Item 1A. Risk Factors

#### **Risk Factors**

Our business faces significant risks. If any of the events or circumstances described in the following risks actually occurs, 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. All references to "Baxter" in these Risk Factors should be read, as to future contingencies, to include Fenwal.

#### The INTERCEPT Blood System may not achieve broad market acceptance.

We may encounter governmental and blood banking community resistance to commercial adoption. Some potential customers may await further safety information or additional studies before choosing whether to adopt our products. There is some loss of platelets as a result of our pathogen inactivation process. If the loss of platelets leads to increased costs, or our process requires changes in blood center or clinical regimens, customers may not adopt our platelet system. Our products do not inactivate all known pathogens, and the inability of our systems to inactivate certain pathogens may limit their acceptance. In addition, our products may not demonstrate economic value sufficient to offset their price, imposing a financial burden on the healthcare system that may limit market acceptance.

For logistical and financial reasons, the transfusion industry has not always integrated new technologies into their processes, even those with the potential to improve the safety of the blood supply, such as the INTERCEPT Blood System. Our products may require significant changes to our potential customers' blood component collection methods, space and staffing requirements and potential customers may not believe that the benefits of using the INTERCEPT Blood System justify their additional cost. In addition, our platelet system process today is not fully compatible with the common practice of collecting two units of platelets from a single apheresis donor. If customers experience operational or technical problems with the use of INTERCEPT Blood System products, market acceptance may be reduced. For example, if adverse events arise from incomplete inactivation of pathogens, improper processing or user error, or if testing of INTERCEPT Blood System-treated blood samples fails to reliably confirm pathogen inactivation, whether or not directly attributable to a shortcoming of the INTERCEPT Blood System, customers may refrain from purchasing the products.

Market acceptance of our products may also be affected by blood center budgets and the availability of reimbursement from governments, managed care payors, such as insurance companies, or other third parties. In many cases, due to the structure of the blood products industry, we will have little control over budget and reimbursement discussions, which generally occur between blood centers and national or regional ministries of health and private payors. It is difficult to predict the reimbursement status of newly approved, novel medical

device products. In certain foreign markets, governments have issued regulations relating to the pricing and profitability of medical products and medical products companies. There also have been proposals in the United States, at both the Federal and state government level, to implement such controls. The widespread adoption of managed care in the United States has also placed pressure on the pricing of medical products. These pressures can be expected to continue and may limit the prices we can obtain for our products.

Product revenue in Europe and other regions may be negatively affected because we do not have FDA approval for any of our products, nor are we prioritizing seeking such approval. Not prioritizing pursuit of regulatory approval of the INTERCEPT Blood System in the United States historically in favor of focusing on commercializing the INTERCEPT Blood System in Europe, Asia and the Middle East may have adverse consequences on market acceptance of the INTERCEPT Blood System globally. If the INTERCEPT Blood System products fail to achieve market acceptance, we may never become profitable.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including oftendominant regional or national blood collection entities. Even if our products receive regulatory approval and reimbursement is available, failure to properly market, promote, distribute, price or sell our products to any of these large customers could significantly diminish potential product revenue in those geographies. The market for our pathogen inactivation systems in the United States is highly concentrated, dominated by a small number of blood collection organizations. In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. In Europe, the largest markets for our products are in England, Germany and France. Decisions on product adoption in England are centralized with the National Blood Service, where general cost containment pressures have delayed consideration of the INTERCEPT Blood System to date. In Germany, decisions on product adoption and subsequent reimbursement are expected to be on a regional or even blood center-by-blood center basis, but depend on both local and centralized regulatory approvals. While the platelet and plasma systems have received in-country regulatory approval in France, adoption throughout France has been delayed pending budget authorization from the French Ministry of Health to support a national contract with the EFS. Blood center economics in certain European countries, including Germany and the United Kingdom, may require that we develop disposable kit configurations of the platelet system that treat larger volumes of platelets, which would serve to reduce the absolute number of kits we might sell to address market demand in those countries, even though our selling price and margin might be higher on such disposable kit configurations. The Japanese Red Cross controls a significant majority of blood transfusions in Japan. If approvals are not obtained to market our products in these countries, or if the products are not adopted in these countries, our potential product revenue will be significantly decreased.

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

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

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

- post-launch surveillance;
- quality;
- 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. In addition, we may be required to obtain approval from the Food and Drug Branch of the California State Department of Health for any product manufactured by us in California, including clinical trial use. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses, or we may not be successful at all.

Before the FDA determines whether to approve the INTERCEPT Blood System products, we expect our approval applications to be reviewed by the Blood Products Advisory Committee, or BPAC. BPAC would then make a recommendation to the FDA for, or against, approval. Even if BPAC were to recommend approval of one or more of our products, the FDA would not necessarily approve those products. If BPAC were to recommend against approval of one or more of our products, it is likely that the FDA would not approve those products. 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 and ISO 13485, a quality management system standard applicable to the products we sell in Europe. The failure to comply with these requirements on an ongoing basis could result in delaying or precluding commercialization efforts in certain geographies, including the United States, and could result in enforcement action, which could harm our business. The current manufacturing sites we rely upon for producing the platelet and plasma system products for European distribution are not FDA-qualified facilities. Regulatory authorities may also require post-marketing testing, which can involve significant expense. Governments or regulatory authorities may impose new regulations or other changes or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval and subsequent adoption of our potential products. We cannot predict the impact of adverse governmental regulation that might arise from future legislative or administrative action.

Distribution of our products outside the United States also is subject to extensive government regulation. These regulations vary by country, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations. In some countries, we may be required to register as a medical device manufacturer, even though we outsource manufacturing to third parties. In addition, countries outside the European Union may require clinical data submissions, registration packages, import licenses or other documentation with which we have no familiarity.

We were required to obtain a CE mark extension in our name from European Union regulators for our platelet system, originally obtained by Baxter in 2002, by May 2007 and will need to do so every five years thereafter. In addition to European Union-level approval, we must obtain regulatory and reimbursement approvals in some individual European countries, including France and Switzerland, to market our products. We may also be required to conduct additional testing in order to obtain regulatory approval in countries that do not recognize the CE mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of additional product testing varies by country, but could be expensive or take a long time to complete. Failure to obtain necessary regulatory approvals or any other failure to comply with regulatory requirements could result in lost product revenue and profitability.

We have conducted many toxicology studies to demonstrate the INTERCEPT platelet and plasma systems' safety, and we have conducted and plan to conduct toxicology studies for the INTERCEPT red blood cell system

throughout the product development process. At any time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products' safety, which could delay commercialization. In addition, the FDA or foreign regulatory authorities may alter guidance at any time as to what constitutes acceptable clinical trial endpoints or trial design, which may necessitate our having to redesign our product candidates or proposed clinical trials and cause us to incur substantial additional expense or time in attempting to gain regulatory approval. 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. We expect the FDA to require us to demonstrate a very low level of potential side effects in data from commercial use or in additional Phase III trials of the platelet system we may conduct in the United States. Trials of this type may be too large and expensive to be practical.

Regulatory delays can also materially impact our product development costs. If we experience delays in testing or approvals, our product development costs will increase. For example, we may need to repeat clinical trials to address regulatory or clinical questions. We may also need to retain third-party investigators and organizations in an attempt to facilitate regulatory review and approval. If the delays are significant, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to become profitable will be delayed.

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

In addition to the regulatory requirements applicable to us and to our products, there are regulatory requirements applicable to our prospective customers of INTERCEPT Blood System products, the blood centers that process and distribute blood and blood products. Blood centers and others will likely be required to obtain approved license supplements from the FDA or European regulatory authorities before making available blood products processed with our pathogen inactivation systems to hospitals and transfusing physicians. For example, our customers in Germany must obtain separate regulatory approvals to manufacture and sell blood components treated with the INTERCEPT Blood System. Our customers may lack the resources or capability to obtain such regulatory approvals. These requirements or regulators' delays in approving license supplements may deter some blood centers from using our products. Blood centers that do submit applications for manufacturing and sale or 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.

If our preclinical and clinical data are not considered sufficient by regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue. Our red blood cell system requires extensive additional testing and development.

Except for the INTERCEPT platelet and plasma systems, which have received CE mark approval and in-country regulatory approvals in certain countries in Europe, we have no products that have received regulatory approval for commercial sale and are being marketed. Our product candidates are in various stages of development, and we face the risks of failure inherent in developing medical devices and biotechnology products based on new technologies. Our product candidates must satisfy rigorous standards of safety and efficacy and we must adhere to quality standards regarding manufacturing and customer-facing business processes before the FDA and international regulatory authorities can approve them for commercial use. We must provide the FDA and international regulatory authorities with preclinical, clinical and manufacturing data demonstrating that our products are safe, effective and in compliance with government regulations before the products can be approved for commercial sale.

In 2002, the platelet system received CE mark approval. We will need to complete validation studies and obtain in-country regulatory approvals and gain national reimbursement in certain European countries before we can market our products in those countries. We expect that lengthy randomized clinical trials funded by a third party will need to be completed prior to our marketing our platelet system in The Netherlands. We also expect to conduct many smaller scale experience studies at our expense with prospective customers in a number of European countries.

We completed our Phase III clinical trial of the platelet system in the United States in March 2001 and have submitted data from this trial, along with several other modules of our pre-market approval application, to the FDA. Based on discussions with the FDA, we performed an additional blinded analysis of the clinical trial data, under the direction of an independent expert physician panel, to determine if apparent differences between treatment groups in the category of pulmonary adverse events reported in the study were attributable to inconsistent event reporting. The reassessment of primary patient records by the expert physician panel showed no statistically significant differences between groups. This reassessment differed from the earlier analysis of adverse events that was based on clinical trial case report forms, which showed statistically significant differences in specific pulmonary events. We submitted a report of the analysis to the FDA for review. The report included conclusions from the expert physician panel. Based upon further discussions with the FDA following submission of that report, we continue to expect that the FDA will require an additional, significantly larger Phase III clinical trial to evaluate the hemostatic efficacy and safety of the platelet system, using the Company's final commercial product design, as compared to conventional platelets. We also understand that our reassessment of our previously completed Phase III clinical trial data will not be sufficient to address the apparent differences observed in that trial between the treatment groups in the category of pulmonary adverse events. We have had several interactions with the FDA subsequent to the final report submission and understand that the FDA may consider non-randomized data derived from commercial use of the platelet system in Europe in conjunction with previously completed Phase III data from randomized clinical trials conducted in the United States. Such data from commercial use will need to be in a form and substance deemed acceptable to the FDA in its sole discretion. There is no assurance that we will be able to reach agreement with the FDA on the data to be collected, that we will be able to collect such data, or that the FDA will find such data from commercial use adequate to answer questions that the FDA has concerning the safety and efficacy of the platelet system. As a result, the FDA may still require a significantly larger randomized, blinded clinical trial than we and Baxter completed in 2001 before a product license application can be finalized and the platelet system considered for approval in the United States. Such an additional Phase III trial would have to be designed to demonstrate no greater frequency in the incidence of such adverse events relative to a control group on a statistically significant basis. The dimensions of such a Phase III trial may be prohibitively large due either to prospective cost, logistics or both. The additional Phase III clinical trial would need to be completed and data from the trial submitted to the FDA before we could complete our regulatory submission. Before we begin gathering data from commercial use in Europe or an additional 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 or we may conclude that the cost of such a study is unacceptable or logistically unachievable. The FDA may not find the data from any additional clinical trials or from commercial use in Europe to be acceptable for approval in the United States. In the United States, studies related to the platelet system disposable and compound manufacturing also need to be completed and included in FDA submissions before the FDA would consider the applications for approval.

We have completed Phase IIIa, Phase IIIb and Phase IIIc clinical trials of the plasma system, in the United States, reports for which were filed with the FDA during 2005. We obtained a CE mark approval in Europe of the plasma system in November 2006 and final French approval in May 2007. We have not submitted any applications for regulatory approval of the plasma system in the United States or any other regions other than Europe. In some countries, including several in Europe, we or our customers may be required to perform additional clinical studies or submit manufacturing and marketing applications 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 antibody reactivity to red blood cells treated with the INTERCEPT red blood cell system in one patient in the chronic arm of the trials, we have been conducting additional research activities on our red blood cell system to determine if the system can be reconfigured to reduce the potential for antibody reactivity to treated red blood cells. Based upon an internal evaluation of the results to date from these additional research activities and after consulting with regulatory authorities, we initiated a new Phase I trial in 2006 in the United States using a modified red blood cell system before potentially progressing to later-stage clinical trials. We utilized a manual processing system in the Phase I trial, which system is not in a commercially feasible form. Results of the Phase I trial suggest that the modified process in combination with a conventional additive solution results in conditions not suitable for long-term storage of red blood cells treated with the INTERCEPT system, adversely impacting their lifespan. Consequently, we are conducting in vitro and in vivo studies and plan to begin a new Phase I clinical trial in the second half of 2008 to test further modifications to the red blood cell system. A number of trial design, process and product design issues that could impact efficacy, regulatory approval and market acceptance will need to be resolved prior to the initiation of further clinical trials and while those clinical trials are being conducted, including determining the appropriate design of additional Phase I or subsequent Phase II clinical trials, if deemed necessary, and Phase III clinical trials, and developing a commercially feasible red blood cell system, including disposables, hardware and software for implementing the process in blood collection centers. These development initiatives may be costly and time consuming. Even if the project proceeds on course, we would not expect to initiate a Phase III trial for our red blood cell system for approximately two years. A delay in completing such activities could result in a delay in the timely progression to later stage trials. If we are unsuccessful in advancing a modified red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our development expenses incurred to date in the red blood cell system program.

Clinical trials in particular are expensive and have a high risk of failure. Any of our product candidates may fail in the testing phase or may not achieve results sufficient to attain market acceptance, which could prevent us from achieving profitability. We do not know whether we will begin and conduct planned clinical trials on schedule, if at all. Significant delays in clinical testing could materially impact our clinical trials. We also do not know whether planned clinical trials will need to be revamped or will be completed on schedule, if at all. Criteria for regulatory approval in blood safety indications are evolving with competitive advances in the standard of care against which new product candidates are judged, as well as with changing market needs and reimbursement levels. Clinical trial design, including enrollment criteria, endpoints, and anticipated label claims are thus subject to change, even if original objectives are being met. In addition to the reasons stated above, clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, delays in reaching agreement on acceptable clinical study agreement terms with prospective clinical sites, delays in obtaining institutional review board approval to conduct a study at a prospective clinical site and delays in recruiting subjects to participate in a study. We do not know whether any clinical trials will result in marketable products. Typically, there is a high rate of failure for product candidates in preclinical and clinical trials and product candidates emerging from any successful trials would not reach the market for several years.

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

## We have very limited experience in marketing and sales, or in managing a commercial operation in Europe. We have limited experience in managing regulatory affairs, particularly with foreign authorities.

Following our agreements with Baxter in February 2006, we became fully responsible for sales, marketing and distribution support of the INTERCEPT Blood System worldwide, except in those Asian territories covered by our agreements with BioOne for the platelet and plasma systems. As a consequence, we no longer rely upon Baxter or Fenwal for sales, marketing, distribution, or regulatory support of the INTERCEPT Blood System. If we fail in our efforts to develop such internal competencies or establish acceptable relationships with third parties on a timely basis, our attempts to commercialize the INTERCEPT Blood System may be irreparably harmed.

### We must develop, build and manage marketing, sales, distribution, customer service and back office functions necessary to support commercialization of the INTERCEPT Blood System in Europe.

Historically, we had a small scientific affairs group that helped support Baxter's European sales and marketing organization; however, we did not maintain our own independent sales and marketing organization. We may be unable to maintain existing customer relationships established by Baxter or Fenwal as we take on responsibility for sales, marketing and customer service. Beginning in early 2006, we began to recruit a small organization headquartered in The Netherlands dedicated primarily to selling and marketing the platelet and plasma systems in geographies where it is approved. We may be unable to recruit suitable sales, marketing, and supporting personnel on a timely basis, if at all, or retain such personnel thereafter. In addition to adding sales and marketing capabilities, we have needed to develop appropriate inventory and logistics management, receivables and collections, foreign exchange, risk management, human resources, information, local regulatory, and quality systems capabilities. Generally, such capabilities must be built in compliance with EU and local standards and practices, with which we have little experience. We also have had to develop customer service capabilities to insure uninterrupted supply of platelet and plasma system disposable kits, timely calibration and servicing of UVA illuminators, and appropriate and timely resolution of customer complaints. We may be unable to operate a European organization effectively and efficiently, even after Cerus Europe B.V. is fully staffed. Developing sales, marketing and operational capabilities ourselves will increase our costs and the rate of cash consumption and may delay commercialization of our pathogen inactivation systems.

### We rely on third parties to market, sell and distribute our pathogen inactivation products and to maintain customer relationships in a number of foreign countries.

We have entered into contracts, generally on a geographically exclusive basis, with distributors in countries where we have limited abilities to commercialize our pathogen inactivation products directly. We have entered into national distribution agreements in Spain and Portugal, Turkey, Russia, Poland, Greece, Kuwait, Saudi Arabia, and Malaysia, as well as regional distribution agreements in Italy. We rely on these distributors to market and sell the INTERCEPT Blood System, provide customer support, maintain inventories, and adhere to our quality system in all material respects, among other activities. While our contracts generally require distributors to exercise diligence, these distributors may fail to commercialize the INTERCEPT Blood Systems in their respective territories or may do so on terms that are not economic to us. They may fail to sell product inventory they have purchased from us to end customers. They may irreparably harm relationships with local existing and prospective customers and our standing with the blood banking community in general. We may have little recourse, short of termination, in the event that a distributor fails to execute according to our expectations.

### We must develop regulatory capabilities for clinical-stage and Phase IV trials involving the INTERCEPT Blood System globally.

Failure to develop such regulatory capabilities may slow the rate of adoption of the platelet and plasma systems. We need additional resources to support regulatory activities and post-approval trials relating to these products. We may not have adequate internal resources and capabilities to manage Phase IV and post-approval trials and to respond appropriately to possible customer complaints or required regulatory reporting of adverse

events arising from the use of the platelet system. We will need to increase our regulatory and trial management resources or contract with independent regulatory consultants, which we may be unable to do on a timely basis. Adding regulatory and trial management resources will result in increased costs and may potentially delay regulatory filings. Delays or inabilities to complete regulatory filings and obtain approvals will also delay or prevent us from being able to recognize sales of our products and attaining profitability.

We will continue to rely on Fenwal for manufacturing and supplying components of our platelet and plasma systems for a limited period of time. Over a longer period, we will need to identify, select and qualify third party sources of supply for the INTERCEPT Blood System, including the INTERCEPT red blood cell system. We are dependent on Fenwal to manufacture the platelet and plasma systems through the end of 2008 and certain components of the two systems through the end of 2009, subject to extension under specified conditions, but have not yet established a source of supply for the INTERCEPT Blood System for 2010 and beyond.

In March 2007 Baxter sold its Transfusion Therapies business, the unit of Baxter that has performed many of the manufacturing and supply chain activities related to our relationship with Baxter, to a new company, Fenwal Inc. We have been informed by Baxter that Fenwal has assumed Baxter's obligations to us under the manufacturing agreement. However, Fenwal may fail to manufacture an adequate supply of components, Intersol additive solution or devices of the INTERCEPT Blood System or to do so on a cost effective basis, which would subject us to the risks described above. Certain components of the INTERCEPT Blood System are currently manufactured or assembled at facilities not owned by Fenwal. Under our agreements, Fenwal will continue to be obligated to supply illuminators and disposable kits associated with the platelet and plasma systems to us generally through 2008 and for certain components through 2009. Failure to produce an adequate supply of components or devices of the INTERCEPT Blood System would subject us to the risks described above. In addition, because the components of the INTERCEPT Blood System are manufactured and assembled at multiple facilities owned by both Fenwal and Baxter leading up to final assembly, Fenwal and Baxter will remain interdependent with respect to the INTERCEPT Blood System supply chain. Fenwal and Baxter may fail to coordinate or meet interdependent supply chain obligations, leading to a failure to manufacture an adequate supply of components or devices of the INTERCEPT Blood System, which would also subject us to the risks described below. While we have had discussions with Fenwal and third parties, we have not successfully concluded negotiations to assure an uninterrupted supply of the INTERCEPT Blood System beyond the expiration of the current supply agreement with Fenwal. Failure to do so would lead to material adverse events, including loss of contracts, customer relationships and our ability to operate as a going concern.

Fenwal manufactures our platelet and plasma systems in facilities that are not FDA-approved. Our agreements do not require Fenwal to validate these manufacturing facilities with the FDA. In order to be sold in the United States, our systems would be required to be manufactured in an FDA-approved facility. FDA validation of a manufacturing facility, whether owned by Fenwal or by another party, will be costly and time-consuming.

### We rely on third parties for manufacturing and supplying components of our platelet and plasma systems.

We will also be dependent on Baxter and Fenwal to transfer know-how relevant to the INTERCEPT Blood System; however, certain of Fenwal's materials, manufacturing processes and methods are proprietary to Fenwal or Baxter. We may be unable to establish alternate sources of supply to Fenwal without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review, which would delay our ability to commercialize the platelet and plasma systems. Fenwal is not obligated to provide support for development and testing of improvements or changes we may make to the INTERCEPT Blood System. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. If we conclude that supply of the INTERCEPT Blood System or components from Fenwal is uncertain, we may choose to build inventories of raw materials or work-in-process

components, which would consume capital resources and may cause our supply chain to be less efficient. We have recently contracted directly with third-party suppliers of certain components to the platelet and plasma systems which Fenwal had used historically in an effort to make the supply of components more reliable, though doing so will increase our investment in raw material and work-in-process inventory and subject us to minimum purchase requirements in 2008. Suppliers of these components may not meet quality specifications we have set, which would cause a disruption in supply and may lead to lost sales and irreparable damage to our customer relationships. Moreover, the inclusion of components manufactured by new suppliers could require us to seek new or updated approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals.

### Our potential remedies against Fenwal and Baxter or other manufacturers may be inadequate in assuring that Fenwal and Baxter meet their contractual obligations.

In the event of a failure by Fenwal, Baxter or other manufacturers to perform their obligations to supply components of the INTERCEPT Blood System to us, damages recoverable by us may be insufficient to compensate us for the full loss of business opportunity. Our supply agreement with Baxter, assumed by Fenwal, and other supply agreements contain limitations on incidental and consequential damages that we may recover. A supplier's potential liability in the event of non-performance may not be sufficient to compel the supplier to continue to act in conformity with our agreements.

### The platelet system is not compatible with some commercial platelet collection methods and platforms and platelet storage solutions.

The equipment and materials used to collect platelets vary by manufacturer and by geographic region. Platelets may be collected from a single donor by apheresis using an automated collection machine. Apheresis devices currently used in the United States and European markets differ, among other characteristics, in their ability to collect platelets in reduced volumes of plasma. Platelet concentrates may also be prepared from whole blood by pooling together platelets from multiple donors. There are two commonly used methods for preparing whole blood platelets: the buffy coat method, which is used extensively in Europe and Canada, and the pooled random donor method, which is used in the United States and to a more limited extent in Europe.

Our system for platelets is designed to work with platelets collected using a proprietary platelet storage solution, called Intersol, manufactured by Fenwal. For platelets collected by apheresis, the INTERCEPT platelet system is most compatible with Fenwal's apheresis platelet collection system, because it facilitates the use of Intersol. For platelets prepared from whole blood, our platelet system is most compatible with the buffy coat collection method, again because this method facilitates the use of Intersol as an additive solution to the platelet concentrate. As a result, we have conducted most of our clinical studies using either Baxter's equipment or buffy coat platelets. More recently, we have begun conducting studies in Europe supporting the use of the platelet system in combination with other collection and preparation platforms. Fenwal may be required to obtain separate regulatory approval for Intersol in the United States and in countries which do not recognize CE mark approval before we would be allowed to sell Intersol to customers of the INTERCEPT Blood System in those countries.

In order to address the entire market in the United States, we would need to develop and test additional configurations of the INTERCEPT platelet system. Our efforts to develop the platelet system were initially focused on apheresis platelets collected on Fenwal's automated collection platform. We estimate that the majority of platelets used in the United States are collected by apheresis, though a significant minority is prepared from pooled random donor platelets derived from whole blood collections. We have made our systems compatible with prevalent commercial platelet collection methods in order to address markets in Europe, Russia and the Middle East, where we have begun to commercialize the INTERCEPT Blood System. In order to gain regulatory approval in certain geographies for a platelet pathogen inactivation system compatible with random donor platelets, we will need to perform additional product development and testing, including additional clinical trials. These development activities would increase our costs significantly, and may not be successful.

Fenwal has committed to us to make Intersol collection and pooling products and conversion kits available to customers. However, Fenwal may not make such products or its apheresis collection system available for sale in certain countries and has elected to discontinue sales efforts for its apheresis collection system in Japan.

Other manufacturers supplying blood component collection platforms to the market may resist our efforts to make the INTERCEPT Blood System compatible with their platforms. Making our platelet system readily compatible with the apheresis collection system manufactured by Haemonetics Corp., a supplier of automated blood collection systems will require certain changes in the Haemonetics device, and there can be no assurance that Haemonetics will undertake this effort on a timely basis or in a commercially reasonable form. Gambro, Inc., or Gambro, another major supplier of automated platelet collection systems, received a CE mark of its own system for pathogen inactivation of platelets in late 2007. For competitive reasons, Gambro may have little or no incentive to make its apheresis collection system compatible with our platelet system. Attaining compatibility with collection platforms manufactured by others may require adaptations to either the INTERCEPT Blood System or to the collection platforms, which may be difficult to engineer, expensive to implement and test, require additional clinical trials, cause delays in regulatory approval and/or be commercially unattractive to pursue. These development activities will increase our costs significantly, and may not be successful. Market acceptance of the INTERCEPT Blood System may be delayed until the system receives regulatory approval for use on such other equipment, if required.

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

The INTERCEPT Blood System products, including many of the components, have been manufactured on a commercial scale on only a limited basis. Fenwal relies on third parties, including Baxter, to manufacture and assemble some of the platelet and plasma system components, many of which are customized and have not been manufactured on a commercial scale. Fenwal has produced some pathogen inactivation systems in modest commercial quantities, but may not be able to manufacture and assemble other systems or in larger quantities, or do so economically. Because of low sales volumes and other reasons, Fenwal's costs to manufacture commercial components for the platelet and plasma systems have been greater than we previously anticipated and may continue to rise. It is uncertain what effect Fenwal's independence from Baxter will have on its cost structure or on transfer prices from Baxter to Fenwal and costs ultimately passed on to us. These issues may result in reducing our potential gross profit margin from platelet and plasma system sales.

We are in the initial stages of commercializing the INTERCEPT Blood System and may not accurately forecast demand for the INTERCEPT Blood System. We may be unable to contract with third parties to supply adequate numbers of platelet and plasma systems and components to meet demand and, as a result, supply to our customers may be interrupted. If Fenwal or third-party manufacturers fail to produce our products or Intersol products satisfactorily, at acceptable costs and in sufficient quantities, we may incur delays, shortfalls and additional expenses, which may in turn result in permanent harm to our customer relations.

Fenwal and we purchase certain key components of the INTERCEPT Blood System from a limited number of suppliers. Contracts for the long-term supply of certain components have not yet been signed. It would be expensive and time-consuming to establish additional or replacement suppliers for these components. Some components of the INTERCEPT Blood System, including components of the UVA illuminator device, are no longer manufactured, which will require Fenwal or us to identify and qualify replacement components and may require that we conduct additional studies, which could include clinical trials, to demonstrate equivalency or validate any required design or component changes. If Fenwal or we are unable to identify and supply replacement components, we may be unable to supply products to our customers. If we were required to redesign the products, our development costs would increase, and our programs and commercialization efforts could be delayed significantly.

We intend to use third-party manufacturers to produce commercial quantities of the chemical compounds to be used in our products. These compounds have not yet been produced in quantities sufficient to support commercialization for all regions in which we may market our products. We have an agreement with a manufacturer to produce commercial quantities of amotosalen, a proprietary compound used in our platelet and plasma systems. We currently do not have any third-party manufacturing agreements in place for commercial production of compounds used in our red blood cell system. Any new or 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 and that its compounds are equivalent to originally licensed compounds in order for us to maintain commercial licensure of our products. It may be difficult or impossible to economically manufacture our products on a commercial scale.

Our platelet and plasma systems have received regulatory approval for two-year shelf lives. Certain existing inventory has a shorter labeled shelf life. We and our distributors may be unable to ship product to customers out of our inventory prior to the expiration of product shelf life, which would require that we destroy or consume the outdated inventory in product demonstration activities at our expense.

We have used prototype components in our preclinical studies and clinical trials of the INTERCEPT red blood cell system and have not completed the components' commercial design. We will be required to identify and enter into agreements with third parties to manufacture the red blood cell system and related blood component storage solutions.

The system disposables and instruments of our red blood cell system that we used in our preclinical studies and clinical trials in the United States historically and those we are now planning to use in an upcoming Phase I red blood cell trial are prototypes of systems to be used in the final products. As a result, we expect regulatory authorities will require us to perform additional preclinical and clinical studies using the commercial versions of the systems to demonstrate the acceptability of the commercial configuration and the equivalence of the prototypes and the commercial products' design, which may increase our expenses and delay the commercialization of our products. We are testing additional modifications of the red blood cell system to improve the lifespan of treated red blood cells. In vitro and in vivo studies of such modifications to the red blood cell system may not be indicative of red blood cell lifespan in humans. Additional early-stage trials will be necessary to determine whether our modifications, including these new approaches, may lead to a product candidate with acceptable commercial characteristics. We also intend to assess whether such modifications would be acceptable clinically, economically and/or operationally to potential customers. We may determine that although the modified red blood cell system may overcome technical issues encountered in the past, it may not be commercially feasible from potential customers' perspectives. If we fail to develop commercial versions of the INTERCEPT red blood cell system on schedule, our potential revenue would be delayed or diminished and our competitors may be able to bring products to market before we do.

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

Except for very limited manufacturing of disposable components, Fenwal is not obligated to provide manufacturing services related to the red blood cell system. We will need to identify parties to provide those manufacturing services related to our red blood cell system. It may be difficult to enter into these types of agreements on reasonable terms. In particular, it will be time-consuming for other manufacturers to develop the capability to manufacture the INTERCEPT Blood System products and blood component storage solutions economically and to gain regulatory approval to do so for commercial use. We may be unable to identify and contract with manufacturers that can make our products cost-effectively, which would delay our efforts to commercialize the red blood cell system, even if we successfully complete clinical development.

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

Baxter and we have licensed to BioOne rights to commercialize the platelet and plasma systems in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore. BioOne is solely responsible for obtaining regulatory approvals, marketing and selling the platelet and plasma systems in those countries. We understand Fenwal has assumed the rights and obligations of Baxter with regard to Baxter's agreements with BioOne. BioOne is dependent on Fenwal for the manufacture and supply of the platelet and plasma systems. We understand that Fenwal has not maintained Baxter's CE mark registration for the platelet system after it expired in mid-2007; however, Fenwal may choose to apply for CE marks for the platelet and plasma systems under its own label. If Fenwal elects not to obtain such CE marks, BioOne will be required to obtain regulatory approval or import licenses on its own in countries within its licensed territory. BioOne may be unable to qualify the platelet and plasma systems for sale in certain countries in its territory in the absence of CE marks being held by Fenwal, even if CE marks are held by us.

BioOne has made little progress to date in commercializing the platelet and plasma systems in Asian territories. Because we only have a minority investment interest in BioOne, we lack the ability to significantly influence BioOne, and are dependent on BioOne's performance to realize milestone and royalty revenue from commercialization of our platelet and plasma systems in those countries. In Japan, regulatory authorities may require our platelet and plasma systems to be widely adopted commercially in Europe or approved by the FDA before the platelet and plasma systems are considered for approval in Japan, which would delay or prevent BioOne from achieving significant product revenue. In July 2007, BioOne raised limited additional capital in order to fund curtailed operations. At these reduced operating levels, BioOne's abilities to commercialize the platelet and plasma systems in its Asian territories will be compromised. There is no assurance that BioOne will be able to attract additional required capital in the future to successfully commercialize those products licensed from Fenwal and us.

If our competitors develop and market products that are more effective than our products and product candidates, our commercial opportunity will be reduced or eliminated. If competitors encounter difficulties or failures in human clinical trials or in commercial settings, we may face additional clinical, regulatory, and commercial challenges.

We expect our products to encounter significant competition. The INTERCEPT Blood System products may compete with other approaches to blood safety currently in use, as well as with future products that may be developed by others. Our success will depend in part on our ability to respond quickly to medical and technological changes brought about by the development and introduction of new products. Product development is risky and uncertain, and we cannot assure you that we will develop our products successfully. Competitors' products or technologies may make our products obsolete or non-competitive before we are able to generate any significant revenue. In addition, competitors or potential competitors may have substantially greater financial and other resources than we have. They may also have greater experience in preclinical testing, human clinical trials and other regulatory approval procedures.

Several companies are developing technologies that are, or in the future may be, the basis for products that will directly compete with or reduce the market for our pathogen inactivation systems. A number of companies are specifically focusing on alternative strategies for pathogen inactivation in platelets and plasma. In Europe, several companies, including Grifols S.A., Octapharma AG and MacoPharma International GmbH, are developing or selling commercial pathogen inactivation systems or services to treat fresh frozen plasma. Navigant Biotechnologies, a wholly owned subsidiary of Gambro Group, is developing a pathogen inactivation system for blood products and has been issued a CE mark for a pathogen reduction system for platelets.

New methods of testing whole 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 our platelet and plasma systems in France and Germany may impact our ability to compete with bacterial testing for platelets. Tests have recently

been approved to detect West Nile Virus in blood products. Other groups are developing rapid, point-of-care bacterial tests, synthetic blood product substitutes and products to stimulate the growth of platelets. Development and commercialization of any of these or other related technologies could limit the potential market for our products.

We may be liable and we may need to withdraw our products from the market if our products harm people. We may be liable if an accident occurs in our controlled use of hazardous materials.

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and pharmaceutical products. We may be liable if any of our products cause injury, illness or death. Although we will have completed rigorous preclinical and clinical safety testing prior to marketing our products, there may be harmful effects caused by our products that we are unable to identify in preclinical or clinical testing. In particular, unforeseen, rare reactions or adverse side effects related to long-term use of our products may not be observed until the products are in widespread commercial use. Because of the limited duration and number of patients receiving blood components treated with the INTERCEPT Blood System products in clinical trials, it is possible that harmful effects of our products not observed in clinical and preclinical testing could be discovered 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. We are subject to risks and costs of product recall, which include not only potential out-of-pocket costs, but also potential interruption to our supply chain. In such an event, our customer relations would be harmed and we would incur unforeseen losses. We maintain product liability insurance, but do not know whether the insurance will provide adequate coverage against potential liabilities. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products.

Our research and development activities involve the controlled use of hazardous materials, including certain hazardous chemicals, radioactive materials and infectious pathogens, such as HIV and hepatitis viruses. Although we believe that our safety procedures for handling and disposing of hazardous materials are adequate and 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.

Virtually all of our research and development activities and the significant majority of our general and administrative activities are performed in or managed from a single site that may be subject to lengthy business interruption in the event of a severe earthquake. We also may suffer loss of computerized information and may be unable to make timely filings with regulatory agencies in the event of catastrophic failure of our data storage and backup systems.

Virtually all of our research and development activities and the significant majority of our general and administrative activities are performed in or managed from our facilities in Concord, California, which are within an active earthquake fault zone. Should a severe earthquake occur, we might be unable to occupy our facilities or conduct research and development and general and administrative activities in support of our business and products until such time as our facilities could be repaired and made operational. Our property and casualty and business interruption insurance in general does not cover losses caused by earthquakes. While we have taken certain measures to protect our scientific, technological and commercial assets, a lengthy or costly disruption due to an earthquake would have a material adverse effect on us. We have also taken measures to limit damage that may occur from the loss of computerized data due to power outage, system or component failure, or corruption of data files. However, we may lose critical computerized data, which may be difficult or impossible to recreate, which may harm our business. We may be unable to make timely filings with regulatory agencies in the event of catastrophic failure of our data storage and backup systems, which may subject us to fines or adverse consequences, up to and including loss of our abilities to conduct business.

#### 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 selling, general, and administrative expenses have resulted in substantial losses each year since our inception with the exception of the year ended December 31, 2005. In 2005, we realized a \$22.1 million nonrecurring gain associated with the restructuring of a loan payable in 2005 and, as a result of this gain, we recorded net income of \$13.1 million in 2005. At December 31, 2007, we had an accumulated deficit of approximately \$356.7 million. Except for the platelet and plasma systems, we have not received significant revenue from product revenue. The platelet and plasma systems are not yet approved in the United States or in many other countries around the world. The red blood cell system is in early stage clinical development and may never emerge from the clinical development stage as a marketed product. We may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, which would reduce and may eliminate our gross profit on sales. Pricing levels may differ widely from country to country, depending on economic, social and industry practices specific to each country. At our present low unit sales levels of the platelet and plasma systems, our costs to manufacture, distribute, market, sell, support and administer the systems are in excess of revenue. We may be unable to increase sales to a level sufficient to generate profit contribution. Because the contracts with large, public-sector customers, such as the EFS, for the INTERCEPT Blood System may not be confidential due to the public tender process, their terms may set contractual precedents that would not be acceptable to us if applied to contracts with our other customers. Historically, we received substantially all of our revenue from our agreements with our development partners and from federal research grants and cooperative agreements and were required to conduct significant research, development, clinical testing and regulatory compliance activities for each of these products. Only in the most recent year ended December 31, 2007, has our product sales revenue exceeded revenue from our agreements with our development partners and from federal research grants and cooperative agreements. Contribution from product sales is unlikely to exceed the costs we incur in research, development, and commercialization of the INTERCEPT Blood System for the foreseeable future. We expect our losses to continue at least until the INTERCEPT Blood System is commercialized more broadly and achieves more significant market acceptance. Costs of developing and testing the red blood cell system in later stage human clinical trials will extend the period during which we expect to operate at a loss.

## 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 and product commercialization efforts are capital-intensive. We may need to reduce or stop further investment in specific research and development or sales and marketing activities if we are unable to obtain additional capital or if any of our development programs are determined by us to be economically unfeasible. A product or program may be determined to be uneconomic if the commercial opportunity is insufficient to justify the investment required to develop and market the product or for other reasons. We expect that our spending in support of research, development and commercialization of the platelet, plasma, and red blood cell systems will be in excess of contribution from product sales and development funding for such programs from third parties over the next year. We may experience higher than anticipated working capital requirements, particularly if we are unable to collect accounts receivable on a timely basis or choose to maintain safety stocks of inventory of the platelet and plasma systems to mitigate risks of supply shortages. As a result of these factors, further product development and commercialization of the INTERCEPT Blood System may take longer and be more expensive than we previously anticipated. We expect to continue to expend substantial funds in support of 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 from collaborators, funding from agencies of the United States government, costs related to creating, maintaining and defending our intellectual property position, regulatory approval and successful commercialization of our product candidates, competitive developments and regulatory factors.

Through December 31, 2007, we had been awarded \$41.7 million in funding under cooperative agreements with the Department of Defense, and have received \$41.3 million in proceeds from these awards. We also

received funding under grants from the National Institutes of Health, largely in support of the immunotherapy business that we spun-off in late 2007. Further funding awarded under federal grants and cooperative agreements for the INTERCEPT Blood Systems will decline significantly when compared to historic levels. It 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. The general economic environment, coupled with tight Federal budgets, has led to a general decline in the amount of government funding. Additionally, we no longer are deemed to be a small business for purposes of being eligible for certain grants administered by the National Institutes of Health and regulated by Small Business Administration. Historically, a significant portion of our grant revenue came from awards surrounding our former immunotherapy business. We anticipate that all grants and awards surrounding our immunotherapy business will be transferred to Anza, and as a result, we will no longer be eligible to receive proceeds from these awards. If we are unable to obtain Federal grant and cooperative agreement funding for future blood safety activities at levels similar to past funding, we may need to reduce our operating expenses, which would delay progress in some of our development programs. In addition, we are required separately to administer and account for our work under government contracts and grants on an on-going basis as a condition to accepting government funding which places administrative, accounting and reporting burdens on us beyond those we have assumed as a public company. If we fail to comply with applicable governmental administrative, accounting and reporting regulations with respect to these grants and cooperative agreements, funds currently available to us may be reduced or lost. These conditions may also result in increased selling, general, and administrative spending beyond what we have experienced.

#### We may receive no economic benefit from the spin-off of our immunotherapy business.

In November 2007, we spun-off our immunotherapy business to Anza Therapeutics, Inc. In exchange for contributed tangible and intangible assets, we received an equity interest of approximately 15.5% of Anza's fully diluted equity, including shares currently held in escrow which we expect to receive. In addition to equity, we are eligible to receive future cash milestone payments of up to in excess of \$90.0 million, as well as royalty payments, if vaccine candidates generated from the transferred assets are successfully developed and commercialized. There is no assurance that the equity will have monetary value at such time we are allowed to sell it or that any of the milestone or royalty payments will ever be made to us.

## 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 there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems, if and when those product are sold in the

United States. Our key blood safety patents generally expire at various dates between 2012 and 2018. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we have a license from Fenwal under United States and foreign patents relating to the INTERCEPT Blood System, which expire from 2010 to 2022. 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.

As our international operations grow, we may be subject to adverse fluctuations in exchange rates between the United States dollar and foreign currencies. Consequently, we may suffer losses.

Our international operations are subject to risks typical of an international business, including, among other factors: differing political, economic, and regulatory climates, different tax structures, and foreign exchange volatility. We do not currently enter into any hedging contracts to normalize the impact of foreign exchange fluctuations. As a result, our future results could be materially affected by changes in these or other factors.

Product sales of our blood safety products are typically made in Europe and generally are invoiced to customers in Euros. In addition, we incur operating expenses in Euros and other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of Interest (Expense) and other, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the U.S. dollar may materially affect our results of operations. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

#### 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, 2005, to December 31, 2007, the sale price of our common stock as quoted on the Nasdaq Global Market fluctuated within a range from a low of \$2.93 to a high of \$14.76. Announcements may have a significant impact on the market price of our common stock. Such announcements may include:

 decisions regarding reimbursement and commercial adoption by customers, national blood services or governmental bodies;

- · biological or medical discoveries;
- technological innovations or new commercial services by us or our competitors;
- developments concerning proprietary rights, including patents and litigation matters;
- regulatory developments in both the United States and foreign countries;
- status of development partnerships;
- dilution from future issuances of common stock, including through the exercise of vested stock options;
- 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.

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accountants attesting to the effectiveness of our internal controls. These requirements extend to the operations of our subsidiary in Europe. If we fail to maintain the adequacy of our internal controls 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 controls 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 the effectiveness of our internal controls over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

#### Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

We lease approximately 21,400 square feet for our main office facility in Concord, California. We exercised a three-year option on the lease for this facility which extends through July 2010, and have an additional option to renew for an additional three-year period. We also have leases for approximately 17,400 square feet, approximately 9,900 square feet, approximately 31,800 square feet, and approximately 4,500 at four other facilities, all of which contain laboratory and office space and are located near our main office facility in Concord. These leases extend through June 2009, January 2010, October 2008, and August 2009, respectively. Our lease for the 9,900 square foot facility contains three one-year renewal options, our lease for the 31,800 square foot facility contains three remaining one-year renewal options, and our lease for the 4,500 square foot facility contains three one-year renewal options. The facility with 31,800 square feet is partially occupied by Anza under a sublease agreement. The remaining facilities are utilized by our blood safety business.

We also lease approximately 7,300 square feet of administrative office space in Amersfoort, The Netherlands, which houses the central operations of Cerus Europe B.V. This lease extends through January 2013. We believe that our current facilities and available additional space will be adequate for the foreseeable future.

#### Item 3. Legal Proceedings

On February 16, 2007, the United States District Court for the Northern District of California granted final approval of the settlement of the class action securities lawsuit that had been pending since 2003 against certain of our current and former directors, officers and us. On February 21, 2007, the Superior Court of Contra Costa granted final approval of the settlement of the derivative lawsuit that had been pending since 2003, in which certain of our current and former directors and officers were named as defendants and the Company was named as a nominal defendant. Both settlements have become effective.

Pursuant to the settlement agreements, the plaintiffs in each case released defendants from all known and unknown claims related to such litigation, without any admission of wrongdoing or liability by any party. Under these settlement agreements, the total cash settlements are funded entirely by insurance carriers under our directors' and officers' liability insurance policy and will have no financial impact on us. Additionally, under the derivative suit settlement, we agreed to take or continue certain corporate governance measures. These measures involved, among others, our making a good faith diligent effort to add one or two independent directors to our Board of Directors by September 1, 2007, (which we achieved by adding one new director in October 2007); and our committing through January 1, 2009, unless otherwise required by law, that two thirds of our Board of Directors will in good faith and with diligent effort consist of independent directors. Under terms of the settlements, we believe that these matters will not have a material effect on our results of operations or financial position.

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

None.

#### PART II

## 1tem 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

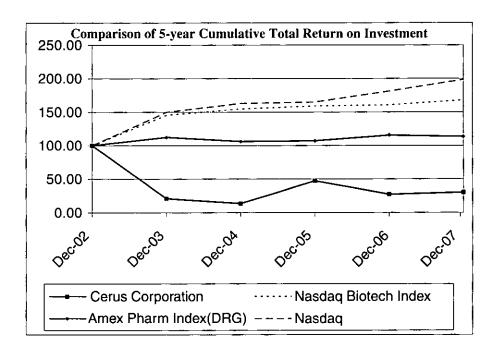
Our common stock is traded on the Nasdaq Global Market under the symbol "CERS." The following table sets forth, for the periods indicated, the high and low sales prices for the common stock as reported by the Nasdaq Global Market:

	High	Low
Year Ended December 31, 2006:		
First Quarter	\$14.76	\$8.10
Second Quarter	8.73	6.29
Third Quarter	7.88	5.27
Fourth Quarter	8.89	\$5.42
Year Ended December 31, 2007:		
First Quarter	7.02	5.11
Second Quarter	8.11	5.11
Third Quarter	9.08	6.05
Fourth Quarter	\$10.29	\$6.17

On February 8, 2008, the last reported sale price of our common stock on the Nasdaq Global Market was \$6.23 per share. On February 8, 2008, we had approximately 188 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.

#### Performance Measurement Comparison

The following graph shows the total stockholder return of an investment of \$100 in cash on December 31, 2002 for (i) our common stock, (ii) the NASDAQ Stock Market (U.S.) Index, (iii) the NASDAQ Pharmaceutical Stocks Index, and (iv) the Amex Pharmaceutical Index. All values assume reinvestment of the full amount of all dividends:



	December 31,						
	2002	2003	2004	2005	2006	2007	
Cerus Corporation	\$100.00	\$ 21.12	\$ 13.72	\$ 47.21	\$ 27.26	\$ 30.28	
NASDAQ Biotech Index	100.00	145.75	154.68	159.06	160.69	168.05	
Amex Pharm Index (DRG)	100.00	112.41	106.06	107.19	115.59	113.40	
NASDAQ	100.00	150.01	162.89	165.13	180.85	198.60	

The graph and other information furnished under this Part II Item 5 of this Form 10-K shall not be deemed to be "soliciting material" or to be "filed" with the Commission or subject to Regulation 14A or 14C, or to the liabilities of Section 18 of the Exchange Act of 1934, as amended.

#### Item 6. Selected Financial Data

The following table summarizes certain selected financial data for the five years ended December 31, 2007. 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. The data presented below may not be indicative of future results.

F		2007		2006		2005		2004		2003
Statement of Operations Date: (1)				(	in th	ousands	)			
Statement of Operations Data: (1) Product revenue	. \$	8,015	\$	2,975	\$	485	\$		\$	52
Other revenue	_	3,029		27,335		13,012		11,317	_	8,598
Total revenue		11,044 5,228		30,310 1,541		13,497		11,317		8,650
Gross profit	_	5,816	_	28,769		13,497	_	11,317	_	8,650
Operating expenses:		,		,		,		,		
Research and development General and administrative		14,957 24,575		16,036 15,082		10,660 10,785		17,990 11,517		46,881 11,929
Impairment of long-term investment in related		·		15,002		10,705		11,517		11,,,2,
party		9,450 —				_		2,861		_
Total operating expenses	_	48,982	_	31,118		21,445	_	32,368	_	58,810
Loss from operations	_	(43,166)	_	(2,349)		(7,948)		$\frac{21,051}{(21,051)}$		(50,160)
Net interest and other income (expense)		4,066	_	4,701		22,405		(4,327)		(4,432)
Net income (loss) from continuing operations Discontinued operations:	\$	(39,100)	\$	2,352	\$	14,457	(	(25,378)		(54,592)
Loss from discontinued operations		(5,820)		(7,131)	i	(1,393)	)	(5,775)		(3,675)
Loss from sale of discontinued operations		(384)					_			
Net loss from discontinued operations		(6,204)	-	(7,131)		(1,393)		(5,775)		(3,675)
Net income (loss)	_	(45,304)	<u>\$</u>	(4,779)	<u>\$</u>	13,064	\$	<u>(31,153)</u>	<u>\$</u>	(58,267)
Net income (loss) from continuing operations per common share:										
Basic		(1.23)		0.09		0.65	-	(1.15)		(2.82)
Diluted  Net (loss) from discontinued operations per common	\$	(1.23)	\$	0.08	\$	0.60	\$	(1.15)	\$	(2.82)
share:										
Basic Diluted		(0.19) (0.19)		(0.27) (0.25)		(0.06) (0.06)		(0.26) (0.26)		(0.19) (0.19)
Net income (loss) per common share:	Φ	(0.19)	Ф			, ,		(0.20)	Ф	, ,
Basic Diluted		(1.42) (1.42)		(0.18) (0.17)		0.58 0.55		(1.41) (1.41)		(3.01)
Weighted average common shares outstanding used for	Φ	(1.42)	Ф	(0.17)	Φ	0.55	Φ	(1.41)	Φ	(3.01)
basic and diluted income (loss) from continuing operations, discontinued operations, and net income										
(loss) per common share:										
Basic Diluted		31,870 31,870		26,870 28,610		22,350 23,950		22,143 22,143		19,367 19,367
Direct		51,070		20,010		23,730		22,173		15,507
	_	2007	_	2006	_	2005	_	2004	_	2003
Balance Sheet Data:				(	in th	ousands)	)			
Cash, cash equivalents and short-term investments Working capital			\$	93,416 87,929		45,805		95,334 23,782	\$	
Total assets		55,582 78,209		115,817		27,690 58,660		23,782 102,078		49,819 118,463
Loan and interest payable		· —		32		4,826		39,000		55,834
Capital lease obligations, less current portion	(	2 356,726)	(	311,422)	(3	68 06,643)	(3	— 319,707)	C	288,554)
Total stockholders' equity	\$	59,887	\$	100,971	\$	35,275	\$	21,489	\$	52,528

<sup>(1)</sup> Historical statement of operation data has been restated to reflect the treatment of our former immunotherapy business as a discontinued operation.

### 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, clinical testing and commercialization of blood safety systems and, from 2001 until late 2007, immunotherapies for cancer and infectious disease. With the exception of a non-recurring gain recognized during the three months ended March 31, 2005, we have been generally unprofitable since inception and, as of December 31, 2007, had an accumulated deficit of approximately \$356.7 million. Except for the platelet and plasma systems, for which we have been issued CE marks, all of our product candidates are in the research and development stage.

To date, our primary source of revenue has been from milestone payments and development contracts and collaborative agreements and grants from U.S. government agencies, including the U.S. Armed Forces and the National Institutes of Health, or NIH. We have recognized modest European product revenues to date from the sale of our platelet and plasma systems. We must conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our product candidates that, together with anticipated general and administrative expenses, are expected to result in substantial losses at least until after our platelet and plasma systems gain widespread commercial acceptance in Europe and the Middle East. Our ability to achieve a profitable level of operations in the future will depend on our ability to successfully commercialize and achieve market acceptance of our blood safety products. We may never achieve a profitable level of operations.

Through December 31, 2007, in addition to the product revenues from sales of our platelet and plasma systems, we have recognized revenue from commercialization agreements with BioOne, as well as from grants and cooperative agreements from the Armed Forces. As a result of selling our immunotherapy business to Anza Therapeutics, Inc., revenue associated with grants and cooperative agreements with the NIH is reported as a component of loss from discontinued operations for all years presented.

Under the agreements with BioOne, we have received milestone payments and may receive additional contingent milestone payments and royalties on future product sales. Prior to the year ended December 31, 2007, we had received a total of \$19.5 million in cash payments and \$10.0 million in equity securities from BioOne as partial payment for licensed rights to commercialize the platelet and plasma systems in certain countries in Asia. In 2007, we reduced the carrying value of our equity in BioOne to \$1.9 million, reflecting the current fair value based on a financing round BioOne completed with third-party investors.

Effective February 1, 2006, we entered into a new agreement with Baxter related to the INTERCEPT Blood System. Under terms of the February 2006 agreement, we gained worldwide rights to the INTERCEPT platelet and plasma systems previously held by Baxter, excluding certain Asian countries covered in agreements with BioOne. We previously acquired worldwide commercialization rights for the red blood cell system from Baxter. Beginning in 2007, we began paying Baxter, and, as of March 2007, Fenwal royalties on product sales, with a rate of 10% of net sales for the platelet system, 3% for the plasma system and 5% for the red blood cell system. This royalty structure replaced the terms of previous agreements with Baxter under which we had received a defined share of gross profit from product sales. Under the terms of the February 2006 agreement, Baxter agreed to supply certain transition services to us through 2006 at our expense, including regulatory, technical and back-office support, and to conduct certain continued development efforts relating to the plasma system at its expense. Baxter also agreed to manufacture systems for the platelet and plasma systems on a cost-plus basis through December 31, 2008, and components through December 31, 2009, and agreed to supply only very limited types of components for the prototype of the red blood cell system. In March 2007, we were informed that Fenwal has assumed Baxter's manufacturing obligations to us.

As a result of the February 2006 agreement with Baxter, we recorded net gains and deferred gains in excess of \$6.5 million and also repaid the \$4.5 million promissory note plus accrued interest owed to Baxter Capital that had originally been due in December 2006. At December 31, 2007, we had recognized all of these gains and deferred gains.

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

#### **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, and non-cash stock compensation assumptions. 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 believe the following critical accounting policies require us to make significant judgments and estimates used in the preparation of our financial statements:

Revenue and research and development expenses—Revenue is recognized when (i) a written agreement exists; (ii) products and/or services have been delivered; (iii) pricing is fixed or determinable; and (iv) collection is probable.

Revenue related to product sales is generally recognized when we fulfill our obligations for each unit of accounting of an agreement. For all INTERCEPT sales, we use a binding purchase order or signed sales contract as evidence of written agreement. We sell INTERCEPT directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, our contracts with customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective product. Deliverables and the units of accounting vary according to the provisions of each customer agreement. For revenue arrangements with multiple elements we evaluate whether the delivered elements have standalone value to the customer, whether the fair value of the undelivered elements is reliably determinable, and whether the delivery of the remaining elements is probable and within our control. When all of these conditions are met, we recognize the revenue on the delivered elements. If these conditions are not met, we defer revenue until such time as all of the conditions have been met or all of the elements have been delivered.

Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the projects are incurred. Revenue related to substantive at-risk milestones specified under development contracts is recognized as the milestones are achieved. To date, we have not received license fees or milestone payments that are refundable. To the extent that they are subject to future performance criteria, we recognize revenue ratably over the estimated license or development period. We have received up-front payments from collaboration agreements. These up-front payments are deferred and recognized over the period where we estimate we are likely to have involvement. We have also received equity in two privately held companies in addition to cash as consideration for licensed rights or technologies. We evaluate several criteria to determine the fair value of the equity received and to conclude whether the facts and circumstances support a fair value for revenue recognition and the investment balance. These criteria include, but are not limited to, third-party investor

interest and participation in recent equity offerings at current pricing, business outlook of the privately held company, and available financial information of the privately held company. The financial information we receive is generally only available on an infrequent basis. Although management uses the best available information at the time, there can be no absolute assurance that facts and circumstances will not change in the future. Should these facts and circumstances change, they may negatively impact our consolidated financial statements. We receive certain United States government grants and contracts 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.

Inventory—We have work-in-progress inventory for certain components of INTERCEPT disposable kits, finished INTERCEPT disposable kits, illumination devices, and certain replacement parts for our illumination devices. Inventory is recorded at the lower of cost, determined on a first in, first out basis, or market value. Our platelet and plasma system kits generally have a two-year shelf life from the date of manufacture, though plasma system disposable kits manufactured prior to early 2007 generally have a one-year life. Subsequent to December 31, 2007, the Company received regulatory approval for two-year life of its plasma system disposable kits. Illumination devices and replacement parts do not have regulated expiration dates. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsaleable. Our limited history selling INTERCEPT limits the amount of historical data we have to perform such analysis. Generally, we write-down specifically identified obsolete, slow-moving, or known unsaleable inventory using a number of factors including product expiration dates, open and unfulfilled orders, forecasts, and inventory turnover.

Accrued expenses—We record accrued liabilities for certain contract research activities and development services, including those related to clinical trials, preclinical safety studies and external laboratory studies, as well as transition services and development activities being performed by third parties. 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. Specifically, accruals for clinical trials require us to make estimates surrounding costs associated with patients at various stages of the clinical trial, pass through costs to clinical sites, contract research organization costs including fees, database development, and reporting costs, among others.

Stock-based compensation—We issue stock-based awards to our employees, Board of Directors, Scientific Advisory Boards and certain contractors as strategic, long-term incentives. Beginning in the first quarter of 2006, we recorded stock-based compensation expense for employee awards under FAS 123R, "Accounting for Stock-Based Compensation" (FAS 123R). We have elected to use the modified-prospective method of adoption. Under FAS 123R, we record compensation expense to our income statement based on the grant-date fair value of a stock award and expense the fair value on a straight-line basis over the requisite service period, which is the vesting period. We determine the grant-date fair value of a stock award using the Black-Scholes option pricing model. We continue to apply the provisions of EITF 96-18, "Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunctions with Selling, Goods or Services" (EITF 96-18) for our non-employee stock-based awards. Under EITF 96-18, the measurement date at which the fair value of the stock-based award is measured is equal to the earlier of 1) the date at which a commitment for performance by the counter party to earn the equity instrument is reached or 2) the date at which the counter party's performance is complete. We recognize stock-based compensation expense for the fair value of the vested portion of the non-employee awards in our consolidated statements of operations.

The Black-Scholes option pricing model calculates the grant-date fair value using certain variables. These variables are impacted by our stock price, award exercise behaviors, the risk free interest rate and our expected dividends and many of these variables require us to use significant judgment.

Expected Term. We estimate the expected term of options granted using a variety of factors. Where
possible, we estimate the expected term of options granted by analyzing employee exercise and post-

vesting termination behavior. To make this estimation, we analyze the population of options granted by discreet homogeneous groups. For those homogeneous groups where we are unable to obtain sufficient information to estimate the expected term in this manner, we estimate the expected term of the options granted by taking the average of the vesting term and the contractual term of the option, as illustrated in the Securities and Exchange Commission Staff Accounting Bulletin No. 107, "Share-Based Payment" ("SAB 107"). The expected term of employee stock purchase plan shares is the average of the remaining purchase periods under each offering period.

- Estimated Forfeiture Rate. We estimate the forfeiture rate of options at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. We estimate the historic pre-vesting forfeiture rates by groups that possess a degree of homogeneity regarding average time to vest and expected term.
- Estimated Volatility. We estimate the volatility of our common stock by using both historical volatility of our common stock and implied volatility in market traded options in accordance with SAB 107. Our decision to use both historical volatility and implied volatility was based upon the limited availability of actively traded options on our common stock and our assessment that due to the limited availability of actively traded options, historical volatility should be given greater prominence in our decision as we believe it is more representative of future stock price. As such, we have calculated our estimated volatility by weighting both historical volatility and implied volatility. We have used significant judgment in making these estimates and we will continue to monitor the availability of actively traded options on our common stock.
- Risk-Free Interest Rate. We base the risk-free interest rate that we use in the option valuation model on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.
- Expected Dividend. We do not anticipate paying any cash dividends in the foreseeable future and therefore use an expected dividend yield of zero in the option valuation model.

If factors change and we utilize different assumptions in determining the grant-date fair value of stock compensation expense in the future, or if we utilize a different option pricing model in the future, then those results may differ significantly from what we have recorded in the current period and could materially effect our operating results. There is significant risk that the Black-Scholes option pricing model and the judgment we have used in ascertaining the variables will yield results that differ materially from the actual values realized upon the exercise, expiration, termination or forfeitures of the awards in the future. Historical results were utilized in deriving our variables, which may not be indicative of the future.

Income Taxes—Since our inception we have accumulated significant net operating losses and research and development credits that may be used in future periods to offset future taxable income. We currently estimate that we may not be able to utilize all of our deferred tax assets. In addition, we may not generate future taxable income prior to the expiration of our net operating loss carry forwards and research and development credits. Timing and significance of any estimated future taxable income is highly subjective and is beyond the control of management due to uncertainties in market conditions, economic environments in which we operate, and timing of regulatory approval of our products. Effective January 1, 2007, Financial Accounting Standards Board Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" (FIN 48), became effective for us. FIN 48 requires derecognition of tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance as described in Financial Accounting Standard 109, "Accounting for Income Taxes" (FAS 109) is not an appropriate substitute for the derecognition of a tax position. The adoption of FIN 48 did not have a significant impact on us. We continue to carry a full valuation allowance on all of our deferred tax assets. Although we believe it more likely than not that a taxing authority would agree with our current tax positions, there can be no assurance that the tax positions we have taken will be substantiated by a taxing authority if reviewed.

#### **Results of Operations**

#### Years Ended December 31, 2007, 2006, and 2005

In the following discussion of our results of operations, results related to the immunotherapy business have been reclassified as discontinued operations for all periods discussed.

#### Revenue

	Years E	nded Decer			
(in thousands, except percentage)	2007	2006	2005	% Change 2007 to 2006	% Change 2006 to 2005
Product revenue	\$ 8,015	\$ 2,975	\$ 485	169%	513%
Government grant and cooperative agreements	3,029	4,836	4,110	(37)%	18%
Milestone and development funding		2,017	1,580	(100)%	28%
Milestone and development revenue from related					
party		20,482	7,322	(100)%	180%
Total revenue	\$11,044	\$30,310	<u>\$13,497</u>	(64)%	125%

Revenue was \$11.0 million in 2007, \$30.3 million in 2006, and \$13.5 million in 2005.

For the year ended December 31, 2007, we recognized \$8.0 million of product revenue from sales of the INTERCEPT Blood System for platelets and plasma, compared to \$3.0 million during the same period in the prior year, and \$0.5 million in 2005. The 2007 increase from 2006 was largely driven by an increase in unit sales of consumable kits and illuminators. Prior to the February 2006 agreements with Baxter, product revenue represented our share of adjusted gross margins on platelet system sales. Subsequent to February 1, 2006, product revenue represents the sales from platelet and plasma systems. The results may not be indicative of platelet and plasma system revenue in the future. We anticipate product revenues for both the platelet and plasma systems will continue to increase in future periods as the INTERCEPT Blood System gains market acceptance in geographies where commercialization efforts are underway.

Revenue from government grants and cooperative agreements decreased by \$1.8 million to \$3.0 million for the year ended December 31, 2007, from \$4.8 million for the comparable period in 2006. The decrease was due primarily to the reduced awards from the Armed Forces for research activities for our INTERCEPT Blood System programs. Revenue increased slightly by \$0.7 million to \$4.8 million for the year ended December 31, 2006, from \$4.1 million during the comparable period in 2005 primarily due to slightly increased development activities surrounding our blood safety awards with the Armed Forces. We anticipate revenues from government grants to make up a declining percentage of our total revenues as we continue to gain market acceptance for the INTERCEPT Blood System.

We recognized no milestone and development funding from Baxter during the year ended December 31, 2007, down from \$2.0 million for the comparable period in 2006. As of January 1, 2007, we no longer receive development funding for cost reimbursement from Baxter. Milestone and development funding increased by \$0.4 million to \$2.0 million for the year ended December 31, 2006, compared to \$1.6 million for the comparable period in 2005. The increase is due to increased development activities for our INTERCEPT plasma product during 2006 in order to obtain CE mark approval.

We recognized no milestone and development funding from BioOne, a related party, during the year ended December 31, 2007, down from \$20.5 million for the comparable period in 2006. When we received up-front consideration from BioOne in 2005, it was initially deferred and was recognized ratably through 2006. In addition, during the year ended December 31, 2006, we received \$9.5 million in milestone funding from BioOne as a result of our receipt of the CE mark approval for the plasma system. At January 1, 2007, we did not have any

remaining deferred revenue from BioOne. We have no further development obligations under our existing agreements with BioOne. We do not expect significant revenues to be generated from BioOne until such time as BioOne may successfully commercialize the products licensed from us, which we expect will be no earlier than 2009, if ever. Milestone and development funding from BioOne increased \$13.2 million to \$20.5 million for the year ended December 31, 2006, compared to \$7.3 million for the comparable period in 2005. The increase was due to the 2006 receipt of \$9.5 million in milestone funding received from BioOne as a result of our receipt of the CE mark approval for the plasma system.

#### Cost of Product Revenue

	Years En	ided Decem	ber 31,		
(in thousands, except percentage)	2007	2006	2005	% Change 2007 to 2006	% Change 2006 to 2005
Cost of Product Revenue	\$5,228	\$1,541	\$	239%	100%

Cost of product revenue increased by \$3.7 million to \$5.2 million for the year ended December 31, 2007 compared to \$1.5 million for the comparable period in 2006, and zero in 2005. The increase of \$3.7 million primarily resulted from increased unit sales of our INTERCEPT platelet and plasma system kits and illuminators in 2007 compared to 2006. In addition, beginning January 1, 2007, we paid royalties to Baxter and then Fenwal, equal to 10% of net platelet system sales and 3% of net plasma system sales. We paid no royalties to Baxter in 2006 or 2005.

Prior to the February 2006 agreement with Baxter, we did not record cost of product revenue or gross margins from product sales. Inventory is accounted for on a first-in, first-out basis. These results may not be indicative of future costs of product sales or gross margins. We anticipate our cost of product revenue to increase in the future as a result of increased product sale volume, royalties that will be owed to Fenwal on platelet and plasma system sales, and as we perform or find alternative service providers for supply chain and back-office order fulfillment services.

#### Research and Development

Our research and development expenses include salaries and related expenses for our scientific personnel, payments to consultants, costs to prepare and conduct preclinical and clinical trials, third-party costs for development activities, certain regulatory costs, costs for licensed technologies, and costs associated with our infrastructure, and laboratory chemicals and supplies. Beginning January 1, 2006, our research and development expenses also include non-cash stock-based compensation as a result of adopting FAS 123R.

	Y ears I	ended Decen	iber 31,		
(in thousands, except percentage)	2007	2006	2005	% Change 2007 to 2006	% Change 2006 to 2005
Research and development	\$14,957	\$16,036	\$10,660	(7)%	50%

Research and development expenses for the year ended December 31, 2007, decreased by \$1.1 million to \$15.0 million from \$16.0 million for the comparable period in 2006. Of the \$15.0 million and \$16.0 million in research and development expenses recognized during the years ended December 31, 2007 and 2006, respectively, \$1.0 million and \$1.1 million, respectively, was due to non-cash stock-based compensation recognized. The primary reasons for the decrease in research and development expenses for the year ended December 31, 2007 compared to 2006 include the decline in development activities associated with our plasma system subsequent to receiving CE mark in November 2006. In addition, during the second half of 2006 we initiated a Phase I clinical trial related to our red blood cell system. Costs associated with this Phase I clinical trial were higher in 2006 than in 2007, the period in which the clinical trial concluded.

Research and development expenses for the year ended December 31, 2006, increased by \$5.4 million to \$16.0 million from \$10.7 million for the comparable period in 2005. In 2005, we did not recognize non-cash stock-based compensation. Additional factors for the increase in research and development expenses during 2006 compared to 2005, include costs incurred to conduct a Phase I clinical trials for the red blood cell system, higher costs associated with the development of the plasma system, as well as an increase in the number of research and development personnel employed.

We anticipate that our research and development spending may increase in the future as a result of clinical trials and system development of our red blood cell system, as well as efforts to support regulatory filings and potential approvals of our platelet and plasma systems in the United States and other countries. Due to the inherent uncertainties and risks associated with developing biomedical products, including but not limited to intense and changing government regulation, uncertainty of clinical study results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete our research and development projects.

#### Selling, General, and Administrative

Selling, general, and administrative expenses include salaries and related expenses for administrative personnel, expenses for our commercialization efforts underway in Europe, expenses for accounting, tax, and internal control, legal and facility related expenses, and insurance premiums. Beginning January 1, 2006, our selling, general, and administrative expenses also include non-cash stock-based compensation as a result of adopting FAS 123R.

	Years l	Ended Decen	nber 31,		
(in thousands, except percentage)	2007	2006	2005	% Change 2007 to 2006	% Change 2006 to 2005
Selling, general and administrative	\$24,575	\$15,082	\$10,785	63%	40%

Selling, general, and administrative expenses increased by \$9.5 million to \$24.6 million for the year ended December 31, 2007, from \$15.1 million for the comparable period in 2006. The increase was mainly due to the costs associated with maintaining and increasing our commercial operations in Europe, representing approximately \$8.8 million of the increase, as well as increased legal, outside professional fees, marketing and travel expenses. For the years ended December 31, 2007 and 2006, respectively, \$1.4 million and \$1.4 million, respectively, was due to non-cash stock-based compensation recognized under FAS 123R.

Selling, general, and administrative expenses increased by \$4.3 million to \$15.1 million for the year ended December 31, 2006, from \$10.8 million for the comparable period in 2005. Of the \$15.1 million of selling, general, and administrative expense recognized during the year ended December 31, 2006, \$1.4 million was due to non-cash stock-based compensation recognized under FAS 123R; no such compensation was not recognized in 2005. Additional factors for the increase in selling, general, and administrative expenses during 2006 compared to 2005, include costs associated with establishing and building our commercial operations in Europe, including increased legal and accounting fees.

Our historical selling, general and administrative results may not be indicative of future selling, general and administrative costs. We anticipate our selling, general, and administrative expenses will continue to increase as we ramp up our INTERCEPT commercialization efforts and continue to work toward broader market acceptance of the INTERCEPT Blood System. We do not anticipate that the sale of the immunotherapy business to Anza Therapeutics will result in significant savings in selling, general, and administrative expenses in the future, as we did not transfer significant selling, general, and administrative assets or personnel to Anza Therapeutics.

#### Gain on Loan Settlement

	Years	Ended De	cember 31,		
(in thousands, except percentage)	2007	2006	2005	% Change 2007 to 2006	% Change 2006 to 2005
Gain on loan settlement	<b>\$</b> —	\$	\$22,089	— %	(100)%

Under an agreement entered into with Baxter in 2005, we repaid \$34.5 million and concurrently entered into a promissory note for \$4.5 million payable with 8% interest as full satisfaction of a loan obligation during the year ended December 31, 2005. As a result of the 2005 agreement, during the year ended December 31, 2005, we recorded a non-operating gain of \$22.1 million. In February 2006, we repaid the \$4.5 million promissory note plus the accrued interest. As of December 31, 2006, we have no further loan obligations.

#### Impairment of Long-term Investment in Related Party

	Years En	ded Decen	nber 31,	% Change	% Change
(in thousands, except percentage)	2007	2006	2005	2007 to 2006	2006 to 2005
Impairment of long-term investment in					
related party	\$9,450	\$	<b>\$</b> —	100%	<del></del>

We recorded an impairment to the carrying value on our investment in BioOne of \$9.5 million during the second quarter of 2007. The impairment represents the difference in our carrying value of the BioOne shares and the fair value of those same shares as a result of BioOne's July 2007 equity financing. If the assumptions we have used to determine the fair value of our investment in BioOne change further, or if BioOne's business deteriorates, we will reassess the fair value of our investment which may result in additional impairment charges.

#### Interest Income (Expense) and Other, Net

	Years E	nded Decem	per 31,	% Change	% Change
(in thousands, except percentage)	2007	2006	2005	2007 to 2006	2006 to 2005
Interest Income (Expense) and Other, Net	\$4,066	\$4,701	\$316	(13)%	1388%

Interest income and other, net decreased by \$0.6 million to \$4.1 million for the year ended December 31, 2007, from \$4.7 million for the comparable period in 2006. The decrease was primarily due to the recognition of a non-operating gain of \$1.8 million during the year ended December 31, 2006, resulting from cash consideration received from Baxter as a component of the February 2006 commercialization transition agreement. In addition, during 2007, we recognized losses on certain marketable securities that we believed were experiencing an other-than-temporary decline in fair value. In determining that each marketable security was experiencing other-than-temporary losses, we considered several factors, including the length and severity of the market decline, the expected length of time for the market prices of each security to approximate our carrying value, and our ability and intent to hold the security for a sufficient period of time to allow the market prices to correct themselves, if ever. The recognized losses adjust our carrying value to the fair value of the securities at December 31, 2007, which will become our basis for recording future gains or losses upon sale or maturity. Partially offsetting this decrease from 2006 was an increase in interest income of \$0.7 million for the year ended December 31, 2007. The increase in interest income was primarily due to consistently higher cash and investment balances maintained during the year ended December 31, 2007, compared to the comparable period in 2006, primarily as a result of our equity offerings in March and December 2006.

Interest income (expense) and other, net was \$4.7 million for the year ended December 31, 2006, and \$0.3 million for the corresponding period in 2005. The increase from 2005 was primarily due to the increase in interest income due to consistently higher cash and investment balances maintained during 2006 from 2005, primarily as a result of our public offerings in 2006. In addition, we recognized a non-operating gain of \$1.8 million during the year ended December 31, 2006, from cash consideration received from Baxter as a result of the February 2006 commercialization transition agreement.

We expect to earn interest income at market rates in proportion to the marketable securities balances we maintain. If the underlying markets for our investments continue to decline or if our liquidity projections change, we may incur additional recognized losses on our investment portfolio.

#### Loss from Discontinued Operations

The results of our former immunotherapy segment are summarized in the following table:

	Years 1	Years Ended December 31,		% Change	% Change
(in thousands, except percentage)	2007	2006	2005	2007 to 2006	2006 to 2005
Revenue Operating expenses	\$ 4,356 10,176	\$ 5,270 12,401	\$10,874 12,267	(17)% (18)%	(52)% 1%
Loss from discontinued operations	(5,820)	(7,131)	(1,393)	(18)%	(412)%
operations	(384)			100%	
Net loss from discontinued operations	\$(6,204)	\$(7,131)	\$(1,393)	(13)%	(412)%

#### **Recent Accounting Standards**

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157 ("SFAS 157"), "Fair Value Measurements," which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of SFAS 157, but do not expect the adoption of SFAS 157 to have a material impact on our consolidated financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS 159"). SFAS 159 permits companies to choose to measure certain financial instruments and certain other items at fair value. SFAS 159 requires that unrealized gains and losses on items for which the fair value option has been elected be reported in earnings. SFAS 159 is effective for us beginning in the first quarter of 2008. We are currently evaluating the impact that SFAS 159 will have on our consolidated financial statements.

In November 2007, the Emerging Issues Task Force (EITF) ratified a consensus on EITF Issue No. 07-1 (EITF 07-1), "Accounting for Collaborative Arrangements", which requires participants in a collaboration to make separate disclosures regarding the nature and purpose of an arrangement, their rights and obligations under the arrangement, the accounting policy for the arrangement and the income statement classification and amounts arising from the arrangement between participants for each period an income statement is presented. EITF 07-1 is effective for us beginning in the first quarter of fiscal year 2009. We are currently evaluating the impact of the provisions of EITF 07-1 on our financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In June 2007, the EITF ratified a consensus on EITF Issue No. 07-3 (EITF 07-3), "Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities", which concluded that non-refundable advance payments for goods or services for use in research and development activities should be deferred and capitalized. EITF 07-3 is effective for us beginning in the first quarter of fiscal year 2008. We are currently evaluating the impact of the provisions of EITF 07-3 on our financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown.

#### **Liquidity and Capital Resources**

Our sources of capital to date have primarily consisted of public offerings and private placements of equity securities, payments received under our agreements with Baxter, BioOne and others, United States government grants and cooperative agreements, product sales and interest income.

At December 31, 2007, we had cash, cash equivalents, short-term investments and marketable securities of \$56.9 million. Net cash used in operating activities was \$37.4 million for the year ended December 31, 2007, compared to \$14.7 million for the same period in 2006. The increase in net cash used in operating activities was primarily due to decreases in our revenues and related cash collections in 2007 compared to 2006, as well as changes in our operating assets and liabilities, notably increases in our inventory purchases. Net cash flows from operations was generally consistent from 2006 to 2005, although changes in our operating assets and liabilities showed variations primarily due to our assumption of INTERCEPT commercialization rights in early 2006. Net cash provided by investing activities during the year ended December 31, 2007, was \$9.3 million, compared to cash used in investing activities of \$7.9 million during the year ended December 31, 2006. The change was primarily due to the maturities of short-term investments, partially offset by the purchases of short-term investments. Net cash provided by financing activities during the year ended December 31, 2007, was \$1.4 million, compared to cash provided by financing activities of \$63.1 million for the same period in 2006. The increase in 2006 compared to 2007 is largely due to the issuance of 5,175,000 shares of common stock in a public offering in March 2006, providing net proceeds of \$42.4 million, and the issuance of 3,903,952 shares of common stock in a registered direct offering in December 2006, providing net proceeds of approximately \$24.3 million, offset by the repayment of a loan from Baxter Capital of \$4.5 million plus accrued interest.

We believe that our available cash balances, together with anticipated cash flows from product sales and existing development and grant arrangements, will be sufficient to meet our capital requirements beyond 2008. These near-term capital requirements are dependent on various factors, including the progress and costs of development and commercialization of the INTERCEPT Blood System, cash collected from product sales, 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 our ability to raise capital through public or private equity or debt financings or through additional collaborative arrangements or government grants, regulatory approval and successful commercialization of the INTERCEPT Blood System and other product candidates, competitive developments and regulatory factors. 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. In March 2006, we completed a public offering of 5,175,000 shares of common stock with gross proceeds, calculated for registration statement purposes, of \$45.3 million under the shelf registration statement. In December 2006, we completed a registered direct offering of 3,903,952 shares of common stock with gross proceeds, calculated for registration purposes, of \$26.1 million under the shelf registration statement.

#### Commitments

The following is a summary of our contractual obligations as of December 31, 2007 (in thousands):

	Payments Due by Period, from December 31, 200						
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years		
Minimum purchase requirements	\$1,456	\$1,406	\$ 50	\$ <b></b> -	<b>\$</b> —		
Operating leases	3,584	1,475	1,537	572			
Total contractual obligations	\$5,040	\$2,881	\$1,587	\$572	<u>\$—</u>		

Our minimum purchase commitments include certain components of our INTERCEPT blood safety system that we purchase from third party manufacturers and provide to Fenwal at no cost.

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

#### Interest Rate 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.

We invest our cash, cash equivalents and short-term investments in a variety of financial instruments, consisting primarily of high credit, high liquidity U.S. government agency securities, commercial paper, corporate debt securities, money market funds and interest-bearing accounts with financial institutions. We maintain portfolio liquidity by ensuring that the securities have active secondary or resale markets. Certain of the investments in our portfolio are subject to general market risk and more specifically, the U.S. mortgage industry. While we believe that we will be able to recognize the fair value of these instruments when they mature or we sell them, there can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these investments are with will be able to meet their debt obligations.

We account for our short-term investments in accordance with SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. Our cash, cash equivalents and short-term investments are all recorded as current assets on our consolidated balance sheets as they are classified as available-for-sale. Securities with remaining maturities at purchase date of less than three months are classified as cash equivalents. The table below presents the amounts and weighted interest rates of our cash, cash equivalents and marketable securities at December 31, 2007 (dollar amounts in thousands):

	Fair Value	Weighted Average Interest Rate
Cash and Cash equivalents (0 – 90 days)	\$19,625	4.76%
Short-term investments (91 days – 1 year)	7,751	5.01%
Short-term investments (1 – 3 years)	29,474	<u>5.24</u> %
Total investments	\$56,850	5.04%

#### Foreign Currency Risk

Our international operations are subject to risks typical of an international business, including, among other factors: differing political, economic, and regulatory climates, different tax structures, and foreign exchange volatility. We do not currently enter into any hedging contracts to normalize the impact of foreign exchange fluctuations. As a result, our future results could be materially impacted by changes in these or other factors.

Product sales for our blood safety products are predominantly made in Europe and generally are invoiced to customers in Euros. In addition, we incur operating expenses, including payment for finished goods inventory of disposable kits for the platelet and plasma systems, generally in Euros and, to a much lesser degree, other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support of our international operations. Foreign exchange rate fluctuations are recorded as a component of Interest income (expense) and other, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the U.S. dollar may materially impact our results of operations. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

#### Item 8. Consolidated Financial Statements and Supplementary Data

Our consolidated financial statements, together with related notes and reports of Ernst & Young LLP, independent registered public accounting firm, are listed in Item 15(a) and included herein.

## Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure None.

#### 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 Rule 13a-15(e) and Rule 15d-15(e), 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, 2007, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in this Annual Report on Form 10-K was (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and (ii) accumulated and communicated to our management, including our principal executive and principal financial officers, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting. During the last quarter of our fiscal year ended December 31, 2007, there were no changes in our internal control over financial reporting during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

Management's Assessment of Internal Control. Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2007, is discussed in the Management's Report on Internal Control Over Financial Reporting included on page 47.

#### Item 9B. Other Information

None.

#### PART III

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

Information regarding our directors and officers, and the compliance of certain reporting persons with Section 16(a) of the Securities Exchange Act of 1934, as amended, will be set forth under the captions "Election of Directors," "Management," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Code of Ethics" in our definitive proxy statement, or proxy statement, for use in connection with the annual meeting of stockholders to be held on June 2, 2008, 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 2007 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.

	Page
Management's Report on Internal Control Over Financial Reporting	47
Reports of Ernst & Young LLP, Independent Registered Public Accounting Firm	48
Consolidated Balance Sheets as of December 31, 2006, and 2007	50
Consolidated Statements of Operations for the three years ended December 31, 2007	51
Consolidated Statements of Stockholders' Equity for the three years ended December 31, 2007	
Consolidated Statements of Cash Flows for the three years ended December 31, 2007	53
Notes to Consolidated 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(4)	Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
3.2 (14)	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.
10.6 (1)	Amended and Restated Investors' Rights Agreement, dated April 1, 1996, among Cerus and certain investors.
10.7 (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.
10.8 (1)	Real Property Lease, dated August 8, 1996, between Cerus and S.P. Cuff.
10.9 (1)	Lease, dated February 1, 1996, between Cerus and Holmgren Partners.
10.10(1)	First Amendment to Common Stock Purchase Agreement, dated December 9, 1996, between Cerus and Baxter Healthcare Corporation.
10.11(2)†	License Agreement, dated as of November 30, 1992, by and among the Company, Miles Inc. and Diamond Scientific Corporation.
10.12(3)	Series B Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation.
10.13(4)	Stockholder Rights Plan, dated November 3, 1999.

Exhibit Number	Description of Exhibit
10.14(13)*	1999 Equity Incentive Plan, as amended, adopted April 30, 1999, approved by stockholders July 2, 1999.
10.15(5)*	Employment Agreement with Howard G. Ervin.
10.16(6)	Lease, dated December 17, 1999 between Cerus and Redwoods Office Center, L.P.
10.17(6)	Lease, dated October 12, 2001 between Cerus and California Development, Inc.
10.18(7)	Loan and Security Agreement, dated November 15, 2002, between Cerus and Baxter Capital Corporation.
10.19(8)*	1999 Non-Employee Directors' Stock Option Sub-Plan, amended December 4, 2002.
10.20(9)†	Collaboration and License Agreement, dated April 20, 2004, between Cerus Corporation and MedImmune, Inc.
10.21(9)*	Employment Agreement, dated August 5, 2004, between Cerus Corporation and Claes Glassell.
10.22(10)*	Employment Agreement, dated July 22, 2004, between Cerus Corporation and William J. Dawson.
10.23(11)†	Restructuring Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.24(11)†	License Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.25(11)†	Manufacturing and Supply Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.26(12)*	Bonus Plan for Senior Management of Cerus Corporation, dated January 1, 2006.
10.27(12)†	Commercialization Transition Agreement, dated as of February 12, 2006, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.28(16)†	Asset Transfer and License Agreement, dated November 20, 2007, by and between Cerus Corporation and Anza Therapeutics, Inc.
10.29(16)*	Offer Letter to Gail Schulze, dated October 15, 2007.
10.30(16)*	Base Salaries for Fiscal Year 2007 for Named Executive Officers.
10.31(15)*	Cerus Corporation Change of Control Severance Benefit Plan.
21.1	List of Registrant's subsidiaries.
23.1	Consent of 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.

<sup>†</sup> Certain portions of this exhibit are subject to a confidential treatment order.

\* Compensatory Plan.

- (1) Incorporated by reference to Cerus' Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
- (2) Incorporated by reference to Cerus' Annual Report on Form 10-K for the year ended December 31, 1997.
- (3) Incorporated by reference to Cerus' Current Report on Form 8-K, dated June 30, 1998.
- (4) Incorporated by reference to Cerus' Current Report on Form 8-K, dated November 3, 1999.
- (5) Incorporated by reference to Cerus' Annual Report on Form 10-K, for the year ended December 31, 2000.
- (6) Incorporated by reference to Cerus' Annual Report on Form 10-K, for the year ended December 31, 2001.
- (7) Incorporated by reference to Cerus' Annual Report on Form 10-K, for the year ended December 31, 2002.
- (8) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2003.
- (9) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.
- (10) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.
- (11) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.
- (12) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2006.
- (13) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.
- (14) Incorporated by reference to Cerus' Current Report on Form 8-K, dated April 26, 2007.
- (15) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.
- (16) Filed herewith.

#### 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, 2007. 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, 2007, the Company's internal control over financial reporting is effective.

The Company's independent registered public accounting firm, Ernst & Young LLP, has audited the effectiveness of internal control over financial reporting as of December 31, 2007. Ernst and Young's attestation report on internal control over financial reporting is included at page 48.

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 Cerus Corporation's internal control over financial reporting as of December 31, 2007, 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, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, 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, Cerus Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cerus Corporation as of December 31, 2007, and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007, and our report dated February 26, 2008, expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP Palo Alto, California February 26, 2008

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

The Board of Directors and Stockholders of Cerus Corporation

We have audited the accompanying consolidated balance sheets of Cerus Corporation as of December 31, 2007, and 2006, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007. 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 consolidated financial position of Cerus Corporation at December 31, 2007, and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U. S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, in fiscal year 2006, Cerus Corporation changed its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment".

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Cerus Corporation's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organization of the Treadway Commission and our report dated February 26, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California February 26, 2008

# CONSOLIDATED BALANCE SHEETS (in thousands, except per share amounts)

	2007	2006
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 19,625	\$ 46,287
Short-term investments	37,225	47,129
Accounts receivable, net of allowance of \$0 at December 31, 2007 and 2006	7,772	5,279
Inventories	7,062	1,833
Prepaid and other current assets	2,218	2,215
Total current assets	73,902	102,743
Property and equipment, net	1,322	1,627
Long-term investment in related party	1,874	11,175
Other assets	1,111	272
Total assets	\$ 78,209	\$ 115,817
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 10,107	\$ 6,665
Accrued liabilities	6,679	7,479
Deferred revenue	1,504	_
Deferred gain		586
Current portion of capital lease obligations	30	84
Total current liabilities	18,320	14,814
Long term portion of capital lease obligations	2	32
Total liabilities	18,322	14,846
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value: 5,000 shares authorized, issuable in series;		
3 shares issued and outstanding at December 31, 2007, and 2006; aggregate		
liquidation preference of \$9,496 at December 31, 2007, and 2006	9,496	9,496
Common stock, \$0.001 par value; 50,000 shares authorized: 32,112 and		
31,734 shares issued and outstanding at December 31, 2007, and 2006,		
respectively	32	32
Additional paid-in capital	407,010	402,888
Accumulated other comprehensive income (loss)	75	(23)
Accumulated deficit	(356,726)	(311,422)
Total stockholders' equity	59,887	100,971
Total liabilities and stockholders' equity	\$ 78,209	\$ 115,817

See accompanying notes.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Years Ended December 31,				31,
	_	2007	2006		2005
Revenue:					
Product revenue	\$	8,015	\$ 2,975	\$	485
Government grants and cooperative agreements		3,029	4,836		4,110
Milestone and development funding		_	2,017		1,580
Milestone and development revenue from related party			20,482		7,322
Total revenue		11,044	30,310	1	3,497
Cost of product revenue		5,228	1,541		
Gross profit		5,816	28,769	1	3,497
Operating expenses:					
Research and development		14,957	16,036		0,660
Selling, general, and administrative		24,575	15,082	l	0,785
Impairment of long-term investment in related party	_	9,450		_	
Total operating expenses		48,982	31,118	_2	1,445
Loss from operations	(	43,166)	(2,349)	(	(7,948)
Interest and other income:				_	<b>3</b> 000
Gain on loan settlement		1000	4.701	2	2,089
Interest income and other, net	_	4,066	<u>4,701</u>	_	316
Net interest and other income	_	4,066	4,701	_2	2,405
Net income (loss) from continuing operations	(	39,100)	2,352	_1	<u>4,457</u>
Discontinued operations:					
Loss from discontinued operations		(5,820)	(7,131)	(	(1,393)
Loss from sale of discontinued operations	_	(384)		_	
Net loss from discontinued operations	_	(6,204)	(7,131)		(1,393)
Net income (loss)	\$(	<u>45,304</u> )	\$(4,779)	\$1	3,064
Net income (loss) from continuing operations per common share:					
Basic	\$	(1.23)	\$ 0.09	\$	0.65
Diluted	\$	(1.23)	\$ 0.08	\$	0.60
Net loss from discontinued operations per common share:					
Basic	\$	(0.19)	\$ (0.27)	\$	(0.06)
Diluted	\$	(0.19)	\$ (0.25)	\$	(0.06)
Net income (loss) per common share:		/1 4 <b>3</b> \	<b>*</b> (0.10.)	•	0.50
Basic	\$		\$ (0.18)		0.58
Diluted	\$	(1.42)	\$ (0.17)	4	0.55
Weighted average common shares outstanding used for basic and diluted income					
(loss) from continuing operations, discontinued operations, and net income					
(loss) per share:  Basic		31,870	26,870	,	22,350
Diluted		31,870	28,610		23,950
Diluted		51,070	20,010	-	25,750

See accompanying notes.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share data)

						Accumulated			
	Prefer	ed Stock	Commo	n Stock	Additional Paid-in	Other Comprehensive	Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)		Deficit	Equity
Balances at December 31, 2004 Issuance of common stock under stock	3	\$9,496	22,210	\$ 22	\$332,002	\$(324)	\$ —	\$(319,707)	\$ 21,489
option and employee stock purchase plans Net change in	_	_	247	1	692			_	693
unrealized loss on investments Net income		_	_	_	_		29 13,064	 13,064	29 13,064
Total comprehensive income							\$ 13,093		
Balances at December 31, 2005	3	9 496	22,457	23	332,694	(295)		(306,643)	35,275
Issuance of common stock, net of expenses of \$2,323		_	9,079	9	66,538	_		—	66,547
Issuance of common stock under stock option restricted stock, and employee stock purchase									
plans			198		1,121 2,535			_	1,121 2,535
unrealized loss on investments				_ 		272 —	\$ 272 (4,779)	 (4,779)	272 (4,779)
Total comprehensive loss							\$ (4,507)		
Balances at December 31, 2006	3	\$9,496	31,734	\$ 32	\$402,888	\$ (23)		\$(311,422)	\$100,971
stock purchase plans Stock-based			378		1,522			_	1,522
compensation Net change in unrealized loss on investments	_	_	_	_	2,600	98	\$ 98	_	2,600 98
Net loss  Total comprehensive	_						(45,304)	(45,304)	(45,304)
loss							\$(45,206)		
December 31, 2007	3	\$9,496 ————	32,112	\$ 32	\$407,010	<u>\$ 75</u>		\$(356,726)	\$ 59,887

See accompanying notes.

# CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)

	Years Ended December 31,			
,	2007	2006	2005	
Operating activities				
Net income (loss)	\$(45,304)	\$ (4,779)	\$ 13,064	
Adjustments to reconcile net income (loss) to net cash used in operating		, , ,		
activities:				
Depreciation and amortization	774	716	652	
Gain on settlement of loan	_		(22,089)	
Stock-based compensation	2,600	2,535	206	
Non-cash equity received in satisfaction of milestone and development				
funding	_	(10,000)	(5,000)	
Loss on sale of equipment	231	_	_	
Impairment of long-term investment in related party	9,450	_	_	
Changes in operating assets and liabilities:				
Accounts receivable and other current assets	(2,493)	(2,293)	(664)	
Inventories	(5,229)	(1,833)	_	
Other assets	(991)	(27)	(160)	
Accounts payable	3,442	4,573	616	
Accrued liabilities	(800)	1,972	510	
Deferred gain	(586)	586	_	
Deferred revenue	1,504	(6,135)	(2,082)	
Net cash used in operating activities	(37,402)	(14,685)	(14,947)	
Investing activities				
Purchases of furniture and equipment	(700)	(1,108)	(856)	
Proceeds from sale of equipment		_	51	
Purchases of short-term investments	(44,481)	(42,310)	(5,000)	
Sales of short-term investments	1,601	_	8,000	
Maturities of short-term investments	52,882	35,478	13,169	
Net cash provided by (used in) investing activities	9,302	(7,940)	15,364	
Financing activities	·	,		
Net proceeds from issuance of common stock	1,522	67,668	693	
Loan repayments	_	(4,500)	(34,500)	
Payments on capital lease obligations	(84)	(36)	1	
Net cash provided by (used in) financing activities	1,438	63,132	(33,806)	
Net increase (decrease) in cash and cash equivalents	(26,662)	40,507	(33,389)	
Cash and cash equivalents, beginning of period	46,287	5,780	39,169	
Cash and cash equivalents, end of period	\$ 19,625	\$ 46,287	\$ 5,780	

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### December 31, 2007

#### 1. Nature of Operations

Cerus Corporation (the "Company") was incorporated on September 19, 1991, and is developing and commercializing the INTERCEPT Blood System, which is designed to enhance the safety of blood components through pathogen inactivation. The Company has licensed commercialization rights for its platelet and plasma systems in parts of Asia to BioOne Corporation ("BioOne").

The Company has received only modest revenue to date from product sales of the INTERCEPT platelet and plasma systems. A substantial majority of the revenue recognized by the Company to date has resulted from the Company's collaboration agreements with Baxter International, Inc. ("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 selling, 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.

#### 2. Summary of Significant Accounting Policies

#### **Principles of Consolidation**

The accompanying audited consolidated financial statements include those of Cerus Corporation and its subsidiary, Cerus Europe B.V. (collectively hereinafter "Cerus" or the "Company") after elimination of all intercompany accounts and transactions. Results of the Company's immunotherapy business, which was sold to a newly-formed company in November 2007, are recorded as a discontinued operation in the accompanying consolidated statements of operations for the three years ended December 31, 2007. As such, results previously reported have been restated to reflect the discontinued operation treatment of the immunotherapy business. The Company also reclassified certain legal costs from research and development to selling, general and administrative for the years ended December 31, 2006 and 2005.

#### 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.

### Revenue and Research and Development Expenses

The Company recognizes revenue in accordance with the SEC's published Staff Accounting Bulletin No. 104, "Revenue Recognition" ("SAB 104") and Emerging Issues Task Force ("EITF") 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables," as applicable. Revenue is recognized when (i) persuasive evidence of an agreement with the funding party exists; (ii) services have been rendered or product has been delivered; (iii) pricing is fixed or determinable; and (iv) collection is probable.

The Company's main sources of revenues through December 31, 2007, have come from its research and development activities and agreements, United States government grants and awards, product revenue from sales

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

of the INTERCEPT Blood System, and commercialization agreements. Effective February 1, 2006, the Company entered into an agreement with Baxter, which gave the Company the exclusive commercialization rights to the INTERCEPT Blood Safety System for platelets and plasma (the "platelet system" and the "plasma system"). As a result of the agreement, the Company now records product revenue of the platelet and plasma systems, rather than the negotiated share of gross profits from such sales under the prior agreement with Baxter. Also as a result of the February 2006 agreement, the Company records cost of product revenues.

Revenue related to product sales is generally recognized when the Company fulfills its obligations for each element of an agreement. For all INTERCEPT Blood System sales, the Company uses a binding purchase order or signed sales contract as evidence of written agreement. The Company sells INTERCEPT Blood System directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, the Company's contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective product. Deliverables and the units of accounting vary according to the provisions of the agreement. For revenue arrangements with multiple elements, the Company evaluates whether the delivered elements have standalone value to the customer, whether the fair value of the undelivered elements is reliably determinable, and whether the delivery of the remaining elements is probable and within the Company's control. When all of these conditions are met, the Company recognizes the revenue on the delivered elements. If these conditions are not met, the Company defers revenue until such time as all of the conditions have been met or all of the elements have been delivered. Consideration received is allocated to elements that are identified as discrete units of accounting based on the relative fair value method. At December 31, 2007, the Company had \$1.5 million of short-term deferred revenue on its consolidated balance sheet. Freight costs charged to customers are recorded as a component of revenue under EITF 00-10, "Accounting for Shipping and Handling Fees and Costs". Value-added-taxes that the Company invoices to its customers and remits to governments are recorded on a net basis, which is excluded from product revenue.

Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the project are incurred. Revenue related to up-front license payments is deferred and recognized ratably over the period of the Company's substantive performance obligation. Revenue related to substantive at-risk milestones specified is recognized as the milestones are achieved. Payments for achieved milestones are non-refundable and are not subject to future performance. Commercialization agreements for the Company consist of agreements for the commercialization of its blood safety products.

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 expenses are charged to expense when incurred. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

The Company's use of estimates in recording accrued liabilities for research and development activities (described previously in this Note under the heading "Use of Estimates") affects the amounts of research and development expenses recorded and revenue recorded from development funding and government grants and collaborative agreements. Actual results may differ from those estimates under different assumptions or conditions.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### **December 31, 2007**

#### 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 (FASB) No. 115, "Accounting for Certain Investments in Debt and Equity Securities," the Company has classified all debt securities as available-for-sale at the time of purchase and reevaluates such designation as of each balance sheet date. Available-for-sale securities are carried at estimated fair value based on quoted market prices. The Company reports the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income (expense) and other, net. The Company's available-for-sale securities consist primarily of U.S. government agency securities and corporate debt securities.

Unrealized gains and losses at December 31, 2007, and 2006 are reported in accumulated other comprehensive income (loss) on the Company's consolidated balance sheets. The Company reviews all of its marketable securities on a regular basis to evaluate whether any security has experienced an other-than-temporary decline in fair value. During the year ended December 31, 2007, the Company recognized losses totaling \$0.2 million associated with investments experiencing an other-than-temporary decline in fair value. These investments primarily relate to fixed income securities of instruments sensitive to the mortgage industry. At December 31, 2007, the Company recorded the fair value of these investments on its consolidated balance sheet which will be the Company's basis in recording prospective unrealized gains and losses. The cost of securities sold is based on the specific identification method.

As of December 31, 2007, the Company also maintained a certificate of deposit for approximately \$0.2 million with a domestic bank. The Company holds this certificate of deposit for any potential decommissioning resulting from the Company's possession of radioactive material. The certificate of deposit is held to satisfy the financial surety requirements of the California Department of Health Services and is recorded within other long-term assets on its consolidated balance sheets at December 31, 2007 and 2006.

#### Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents, short-term investments and accounts receivable.

Substantially all of the Company's cash, cash equivalents and short-term investments are maintained pursuant to the Company's investment policy by two major financial institutions of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and type of investments that exist within its investment portfolio. All of the Company's investments carry high credit quality ratings, in accordance with its investment policy. At December 31, 2007, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company's cash equivalents and short-term investments.

Concentrations of credit risk with respect to trade receivables exist to the full extent of amounts presented in the consolidated financial statements. The Company performs ongoing credit evaluations of its customers and does not require collateral from its customers to secure accounts receivable. The Company provides an allowance for estimated losses on receivables based on a review of the current status of existing receivables and historical collection experience, and such losses have been within management's expectations.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

**December 31, 2007** 

#### **Inventories**

At December 31, 2007, inventory consists of finished goods of INTERCEPT disposable kits, components thereof, illumination devices, and certain replacement parts for the illumination devices. Inventory is recorded at the lower of cost, determined on a first in, first-out basis, or market value. Platelet and plasma system disposable kits generally have a two-year life from date of manufacture, though plasma system disposable kits manufactured prior to early 2007 generally have a one-year life. Subsequent to December 31, 2007, the Company received regulatory approval for two-year life of its plasma system disposable kits. The Company periodically reviews the composition of inventory in order to identify obsolete, slow-moving or otherwise unsalable items. To the extent unsalable items are observed and there is no alternative use, the Company will record a write-down to net realizable value in the period that the impairment is first recognized. At December 31, 2007, the Company had written down approximately \$0.2 million associated with potentially obsolete or expiring product.

#### Property and Equipment, net

Property and equipment is comprised of furniture, equipment, information technology hardware and software and is recorded at cost. At the time the property and equipment is ready for its intended use, it is depreciated 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.

#### **Long-Term Investment**

The Company accounted for its long-term investment under the either the cost method of accounting or equity method of accounting in accordance with Accounting Principles Bulletin No. 18, "The Equity Method of Accounting for Investments in Common Stock" ("APB 18"), and Financial Accounting Standards Board Interpretation No. 35, "Criteria for Applying the Equity Method of Accounting for Investment in Common Stock" ("FIN 35"). At December 31, 2007, the Company held approximately 13% interest in the voting securities of BioOne Corporation ("BioOne") and accounted for its investment in BioOne under the cost method. At December 31, 2006, and through June 30, 2007, the Company held approximately 20% of the voting securities of BioOne. The Company regularly evaluates several criteria in determining whether or not it has the ability to exercise significant influence over the operating and financial policies of BioOne. These criteria include but are not limited to: limited availability of and infrequency of access to financial information of BioOne, majority shareholder mix in BioOne, and the Company's lack of representation on BioOne's board of directors. As a result of its evaluations, at December 31, 2007 and 2006, the Company has accounted for its investment under the cost method, as it has concluded that predominant evidence exists to support this conclusion.

In July, 2007, BioOne completed an equity financing on terms reflecting a valuation substantially below the valuations of previous rounds of financing. As a consequence, the Company recorded a \$9.5 million non-cash impairment charge on the carrying value of its equity interest in BioOne during the three months ended June 30, 2007. The Company's investment in BioOne is included in long-term investments in related party on its balance sheets at the estimated fair value of \$1.9 million at December 31, 2007. To the extent that the criteria used to support the carrying value of the Company's investment in BioOne's equity at December 31, 2007, change further, the Company will need to reassess the recorded basis of its investment in BioOne.

#### **Foreign Currency Remeasurement**

The functional currency of the Company's foreign subsidiary is the U.S. Dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. Dollars using the exchange rates at the

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. Dollars using historical exchange rates. Revenues and expenses are remeasured using average exchange rates prevailing during the period. Remeasurements are recorded in the Company's consolidated statements of operations as a component of interest income and other, net. The Company recorded \$0.7 million in foreign currency gains during the year ended December 31, 2007 and \$0.1 million in foreign currency losses during the year ended December 31, 2006.

## **Stock-Based Compensation**

The Company maintains stock compensation plans as long-term incentives for employees, contractors, members of the Board of Directors, and Scientific Advisory Board. These plans allow for the issuance of non-statutory and incentive stock options, rights to acquire restricted stock, and stock bonuses. The Company also maintains an active employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code.

Beginning January 1, 2006, the Company adopted the provisions of, and accounts for stock-based compensation in accordance with, the FASB's Statement of Financial Accounting Standards No. 123R ("FAS 123R"), "Share-Based Payment," which replaced Statement of Financial Accounting Standards No. 123 ("FAS 123"), "Accounting for Stock-Based Compensation" and supersedes APB Opinion No. 25 ("APB 25"), "Accounting for Stock Issued to Employees." Under the fair value recognition provisions of FAS 123R, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. The Company elected the modified-prospective method, which requires that compensation expense be recorded for the vesting of all non-vested stock options and other stock-based awards at the beginning of the first quarter of adoption of FAS 123R. In accordance with the modified-prospective method, no prior period amounts have been restated to reflect our adoption of FAS 123R.

Total stock-based compensation recognized on the Company's consolidated statements of operations for the years ended December 31, 2007 and 2006, impacted loss per share by \$0.08 per share and \$0.09 per share, respectively.

See Note 10 for further information regarding our stock-based compensation assumptions and expenses, including pro forma disclosures for prior periods as if the Company had recorded stock-based compensation expense.

On November 10, 2005, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. FAS 123(R)-3, "Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards." The Company has elected to adopt the alternative transition method provided in the FASB Staff Position for calculating the tax effects (if any) of stock-based compensation expense pursuant to SFAS 123R. The alterative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee stock-based compensation, and to determine the subsequent impact to the APIC pool and the consolidated statements of operations and cash flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123R.

The Company continues to apply the provisions of EITF 96-18, "Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" (EITF 96-18) for its non-employee stock-based awards. Under EITF 96-18, the measurement date at which the fair value of the

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

stock-based award is measured is equal to the earlier of 1) the date at which a commitment for performance by the counter party to earn the equity instrument is reached or 2) the date at which the counter party's performance is complete. The Company recognizes stock-based compensation expense for the fair value of the vested portion of the non-employee awards in its consolidated statements of operations.

#### Other Comprehensive Income (Loss)

Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" establishes the standards of reporting and displaying comprehensive income (loss) and its components in the consolidated financial statements. The components of comprehensive income (loss) include net income (loss) and other comprehensive income (loss). The Company's only component of other comprehensive income (loss) for the years ended 2007, 2006, and 2005 consisted of unrealized gains or losses from the Company's available-for-sales short-term investments. Other comprehensive income (loss) is reported as a separate component of stockholders' equity.

#### **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. Effective January 1, 2007, Financial Accounting Standards Board Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48") became effective for the Company. FIN 48 requires derecognition of tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance as described in FAS 109 is not an appropriate substitute for the derecognition of a tax position. Upon adoption of FIN 48, the Company's policy to include interest and penalties related to unrecognized tax benefits within our provision for income taxes did not change. The adoption of FIN 48 has not resulted in any significant impact to the Company. The Company continues to carry a full valuation allowance on all of its deferred tax assets. The tax years 2003 through 2006 remain subject to examination by the taxing jurisdictions to which the Company is subject.

#### Net Income (Loss) Per Share—Basic and Diluted

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings (loss) per share reflects the assumed conversion of all dilutive securities, such as options, restricted stock units and convertible preferred stock.

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

	2007	2006	2005
Denominator:			
Basic weighted average number of common shares outstanding	31,870	26,870	22,350
Effect of dilutive potential common shares resulting from stock options,			
unvested restricted common stock and ESPP shares		1,740	1,600
Diluted weighted average number of common shares outstanding	31,870	28,610	23,950

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### **December 31, 2007**

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

	2007	2006	2005
Antidilutive securities—weighted average shares	5,649	3,466	1,713

#### **Guarantee and Indemnification Arrangements**

The Company recognizes the fair value for guarantee and indemnification arrangements issued or modified by the Company after December 31, 2002, if these arrangements are within the scope of Financial Accounting Standards Board Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" ("FIN 45"). In addition, the Company monitors the conditions that are subject to the guarantees and indemnifications, as required under previously existing generally accepted accounting principles, in order to identify if a loss has occurred. If the Company determines it is probable that a loss has occurred, then any such estimable loss would be recognized under those guarantees and indemnifications. Some of the agreements of the Company contain provisions that indemnify the counter party from damages and costs resulting from claims that the Company's technology infringes the intellectual property rights of a third party or claims that the sale or use of the Company's products have caused personal injury or other damage or loss. 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.

The Company generally provides for a one-year warranty on certain of its INTERCEPT blood-safety products covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims become probable and estimable. There have been no warranty costs incurred through December 31, 2007. Accordingly, at December 31, 2007, the Company has not accounted for any potential warranty costs.

#### Fair Value of Financial Instruments

The carrying amounts of accounts receivables, accounts payable, and other accrued liabilities approximate their fair values due to the relative short-term maturities. The carrying amount of the Company's capital lease obligations approximate their fair value based upon management's best estimates of interest rates that would be available for similar debt obligations at December 31, 2007 and 2006. The carrying amounts and fair value of the Company's short term investments and long term investment in related party are described elsewhere in the notes to the consolidated financial statements.

#### **New Accounting Pronouncements**

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157 ("SFAS 157"), "Fair Value Measurements," which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of SFAS 157, but does not expect the adoption of SFAS 157 to have a material impact on its consolidated financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS 159"). SFAS 159 permits companies to choose to

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

measure certain financial instruments and certain other items at fair value. The standard requires that unrealized gains and losses on items for which the fair value option has been elected be reported in earnings. SFAS 159 is effective for the Company beginning in the first quarter of 2008. The Company is currently evaluating the impact that SFAS 159 will have on its consolidated financial statements.

In November 2007, the Emerging Issues Task Force (EITF) ratified a consensus on EITF Issue No. 07-1 (EITF 07-1), "Accounting for Collaborative Arrangements", which requires participants in a collaboration to make separate disclosures regarding the nature and purpose of an arrangement, their rights and obligations under the arrangement, the accounting policy for the arrangement and the income statement classification and amounts arising from the arrangement between participants for each period an income statement is presented. EITF 07-1 is effective for the Company beginning in the first quarter of fiscal year 2009. The Company is currently evaluating the impact of the provisions of EITF 07-1 on its financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown at this time.

In June 2007, the EITF ratified a consensus on EITF Issue No. 07-3 (EITF 07-3), "Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities", which concluded that non-refundable advance payments for goods or services for use in research and development activities should be deferred and capitalized. EITF 07-3 is effective for the Company beginning in the first quarter of fiscal year 2008. The Company is currently evaluating the impact of the provisions of EITF 07-3 on its financial position, results of operations and cash flows and therefore, the impact of the adoption is unknown.

#### Note 3. Cash, Cash Equivalents and Short-Term Investments

The following is a summary of cash, cash equivalents and short-term investments at December 31 (in thousands):

		2007	
	Adjusted Carrying Value	Unrealized Gain (Loss)	Fair Value
Cash and cash equivalents:			
Cash	\$ 2,404	<b>\$</b> —	\$ 2,404
Money Market funds	8,134	_	8,134
Commercial paper	9,087		9,087
Total cash and cash equivalents	19,625	_	19,625
Short-term investments			
Corporate debt securities	25,019	(3)	25,016
Commercial paper	5,313	2	5,315
U.S. government agency securities	6,818	<u>76</u>	6,894
Total short-term investments	37,150	75	37,225
	\$56,775	\$ 75	\$56,850

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

	2006		
	Adjusted Carrying Value	Unrealized Gain (Loss)	Fair Value
Cash and cash equivalents:			
Cash	\$ 5,733	<b>\$</b> —	\$ 5,733
Money Market funds	29,979	_	29,979
Commercial paper	10,575		10,575
Total cash and cash equivalents	46,287	_	46,287
Short-term investments			
Corporate debt securities	27,615	(6)	27,609
Commercial paper	14,467	2	14,469
U.S. government agency securities	5,070	<u>(19</u> )	5,051
Total short-term investments	47,152	(23)	47,129
	\$93,439	<u>\$ (23)</u>	\$93,416

Short-term investments and cash equivalents consisted of the following by original contractual maturity (in thousands):

	2007	2006
Due in one year or less	\$24,972	\$59,144
Due greater than one year and less than three years	29,474	28,539
	\$54,446	\$87,683

Gross proceeds and the realized losses from the sale of available-for-sale investments totaled \$1.4 million and \$0.2 million, respectively, during the year ended December 31, 2007, and were not material during the years ended December 31, 2006 and 2005. Realized losses for other-than-temporary declines in market value totaled \$0.2 million during the year ended December 31, 2007. The Company did not record any other-than temporary declines in market value during the years ended December 31, 2006 and 2005. Realized gains and losses from the sale of available-for-sale investments and from other-than-temporary declines in market value are recorded in Interest income (expense) and other, net.

#### Note 4. Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2007	2006
Leasehold Improvements	\$ 7,772	\$ 7,765
Laboratory Equipment	2,245	4,244
Office Equipment	677	737
Office Furniture	702	658
Computer Equipment	587	601
Computer Software	706	635
Construction-in-Progress	129	5
	12,818	14,645
Less accumulated depreciation and amortization	(11,496)	(13,018)
	\$ 1,322	\$ 1,627

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

#### Note 5. Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2007	2006
Work in progress	\$ 715	\$ —
Finished goods		1,833
	\$7,062	\$1,833

#### Note 6. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2007	2006
Accrued compensation and related	\$2,157	\$2,124
Accrued contract and other accrued expenses	4,522	5,355
	\$6,679	\$7,479

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#### Note 7. Loan Payable to Baxter Capital Corporation

In January 2003, the Company received proceeds from a \$50.0 million loan from Baxter Capital, a financial subsidiary of Baxter International Inc. separate from Baxter. The interest rate on the loan was 12% per annum. Under the terms of the loan, no payment of principal or interest was due until 2008. The loan was secured by the Company's current and future accounts receivable from sales of the platelet system under the agreement with Baxter.

In October 2003, Baxter Capital commenced legal proceedings against the Company seeking immediate repayment of amounts outstanding under the loan. Baxter Capital alleged that changes in the Company's business constituted a default under the loan agreement. The Company did not agree that any default occurred and therefore believed that, under the terms of the loan, no principal or interest payments should be due until January 2008.

Concurrent with the 2005 restructured agreements between Baxter and the Company, Baxter Capital and the Company entered into an agreement under which the Company immediately paid \$34.5 million to Baxter Capital and entered into a promissory note for \$4.5 million, payable with 8% interest. Baxter Capital agreed to accept these payments in full satisfaction of the loan obligation, and the parties dismissed all related legal actions. As a result of the 2005 restructured agreements, the Company recorded net gains of approximately \$22.1 million in its consolidated statement of operations for the year ended December 31, 2005.

During the year ended December 31, 2006, we repaid the \$4.5 million note payable and the related interest of \$0.3 million, reflecting the terms of the February 2006 Commercialization Transition Agreement with Baxter (see Note 11 for additional background on this agreement).

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

#### Note 8. 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 if those renewal options are exercised. Capital lease obligations represent the present value of future rental payments under capital lease agreements for information technology hardware.

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

Year ending December 31,	
2008	\$1,475
2009	,
2010	
2011	
2012 and thereafter	286
Total minimum lease payments	\$3,584

Rent expense for office facilities was \$1.5 million, \$1.2 million and \$1.1 million for the years ended December 31, 2007, 2006, and 2005, respectively.

The Company's total non-cancelable commitments at December 31, 2007 are as follows (in thousands):

	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Minimum purchase requirements	\$1,456	\$1,406	\$ 50	\$ <del></del>	\$ <del></del> -
Operating leases	3,584	1,475	1,537	572	
Total contractual obligations	\$5,040	\$2,881	\$1,587	\$572	<u>\$—</u>

Minimum purchase commitments include certain components of INTERCEPT blood safety system which the Company purchases from third party manufacturers and provides to Fenwal at no cost. The Company paid \$0.9 million, \$0.1 million, and \$0.1 million under the terms of the minimum purchase commitments during the years ended December, 31, 2007, 2006, and 2005, respectively.

#### Litigation

On February 16, 2007, the United States District Court for the Northern District of California granted final approval of the settlement of the class action securities lawsuit that had been pending since 2003 against certain of the Company's current and former directors, officers and the Company. On February 21, 2007, the Superior Court of Contra Costa County granted final approval of the settlement of the derivative lawsuit that had been pending since 2003, in which certain of the Company's current and former directors and officers were named as defendants and the Company was named as a nominal defendant. Both settlements have become effective.

Pursuant to the settlement agreements, the plaintiffs in each case released defendants from all known and unknown claims related to such litigation, without any admission of wrongdoing or liability by any party. Under these settlement agreements, the total cash settlements are funded entirely by insurance carriers under the

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### **December 31, 2007**

Company's directors' and officers' liability insurance policy and will have no financial impact on the Company. Additionally, under the derivative suit settlement, the Company agreed to take or continue certain corporate governance measures. These measures involved, among others, the Company's making a good faith diligent effort to add one or two independent directors to its Board of Directors by September 1, 2007, (which has now been achieved by the addition of one new director); and its committing through January 1, 2009, unless otherwise required by law, that two thirds of its Board of Directors will in good faith and with diligent effort consist of independent directors. Under terms of the settlements, the Company believes that these matters will not have a material effect on its results of operations or financial position.

#### Note 9. Stockholders' Equity

#### **Common Stock Offerings**

In March 2006, the Company completed a public offering of 5,175,000 shares of common stock, which included the underwriters' exercise of their over-allotment option, resulting in net cash proceeds of approximately \$42.4 million. In December 2006, the Company completed a registered direct offering of 3,903,952 shares of common stock, resulting in net cash proceeds of approximately \$24.3 million.

#### Series B Preferred Stock

Baxter holds 3,327 shares of the Company's Series B preferred stock. The holder of Series B preferred stock has no voting rights, except with respect to the authorization of any class or series of stock having preference or priority over the Series B preferred stock as to voting, liquidation or conversion or with respect to the determination of fair market value of non-publicly traded shares received by the holder of Series B stock in the event of a liquidation, or except as required by Delaware law. At any time, the holder may convert each share of Series B preferred stock into 100 shares of the Company's common stock. If all shares of Series B preferred stock were converted to common stock, 332,700 shares of common stock would be issued, which represents approximately 1% of the outstanding common shares of the Company at December 31, 2007. 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.

#### Note 10. - Stock-Based Compensation

The Company maintains stock compensation plans as long-term incentives for employees, contractors, and members of its Board of Directors and Scientific Advisory Boards. Currently, the Company's active stock option plans include the 1998 Non-Officer Stock Option Plan (the "1998 Plan"), and the 1999 Equity Incentive Plan (the "1999 Plan").

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

The 1998 Plan

Under the terms of the 1998 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 1999 Plan

The 1999 Plan provides for grants of ISOs to employees and NSOs, stock bonuses and restricted stock purchase awards to the Company's employees, directors and consultants. The option term is ten years.

#### Employee Stock Purchase Plan

The Company also maintains an 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 Company's 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.

#### Restricted Stock Units

In March 2004, the Company granted restricted stock units to certain then-current employees. Subject to each grantee's continued employment, shares underlying restricted stock unit grants vest in four semi-annual installments. 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. As of December 31, 2007, all restricted stock units pertaining to the March 2004 grants had vested and all related compensation expense had been recognized based on the grant-date valuation of \$3.38 per share.

During the years ended December 31, 2007 and 2006, the Company granted restricted stock units to its Chief Executive Officer and Vice Presidents in accordance with the bonus plan. Subject to each grantee's continued employment, shares underlying the grants vest in three annual installments and are issuable at the end of the three-year vesting term. The restricted stock units granted during the year ended December 31, 2006, totaled 37,098 units and were valued at \$10.32 per unit, or approximately \$0.4 million. 12,366 of the restricted stock units issued during the year ended December 31, 2006, were vested as of December 31, 2007. The restricted stock units granted during the year ended December 31, 2007, totaled 60,620 units and were valued at \$5.54 per unit, or approximately \$0.3 million. None of the restricted stock units issued during the year ended December 31, 2007, were vested as of that date.

The Company adopted FAS 123R in 2006. The Company currently uses the Black-Scholes option pricing model to determine the fair value of stock options and employee stock purchase plan shares. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by the Company's stock price as well as assumptions regarding a number of complex and subjective variables. The variables used to calculate the fair value of stock based payment awards using the Black-Scholes option pricing model, include expected price volatility of the Company's common stock, actual and projected employee stock option exercise behaviors, including forfeitures, the risk-free interest rate and expected dividends.

#### Expected Term

The Company estimates the expected term of options granted using a variety of factors. Where possible, the Company estimates the expected term of options granted by analyzing employee exercise and post-vesting

termination behavior. To make this estimation, the Company analyzes the population of options granted by discreet, homogeneous groups. For those homogeneous groups where the Company is unable to obtain sufficient information to estimate the expected term for a particular group, the Company estimates the expected term of the options granted by taking the average of the vesting term and the contractual term of the option, as illustrated in Staff Accounting Bulletin No. 107 ("SAB 107") "Share Based Payment." The expected term of Purchase Plan shares is the term of each purchase period.

#### Estimated Forfeiture Rate

The Company estimates the forfeiture rate of options at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. The Company estimates the historic pre-vesting forfeiture rates by groups that possess a degree of homogeneity regarding average time to vest and expected term.

#### Estimated Volatility

The Company estimates the volatility of its common stock by using a blended rate of both historical volatility of its common stock and implied volatility in market traded options in accordance with SAB 107. The Company's decision to use both historical volatility and implied volatility was based upon the limited availability of actively traded options on its common stock and the Company's assessment that due to the limited availability of actively traded options, historical volatility should be given greater prominence in its decision as the Company believes historic volatility is more representative of future stock price. As such, the Company has calculated the estimated volatility of its common stock by weighting both historical volatility and implied volatility. The Company has used significant judgment in making these estimates and will continue to monitor the availability of actively traded options on its common stock.

#### Risk-Free Interest Rate

The Company bases the risk-free interest rate that it uses in the option valuation model on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

#### Expected Dividend

The Company does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero in the option valuation model.

The assumptions used to value option grants for each of the three years ended December 31, 2007 are as follows:

	2007	2006	2005
Expected term (in years)	4.16-6.73	4.01-6.28	5.00
Volatility	59.1%	64.6%	59.9%
Risk-free interest rate	4.03%	4.62%	4.32%

The assumptions used to value employee stock purchase rights for each of the three years ended December 31, 2007 are as follows:

	2007	2006	2005
Expected term (in years)	0.5	0.5	0.5
Volatility	54.6%	57.1%	59.0%
Risk-free interest rate	4.4%	4.8%	4.4%

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

Total stock-based compensation recognized on the Company's consolidated statement of operations for the years ended December 31, 2007 and 2006 was classified as follows (in thousands):

	December 31,	
	2007	2006
Research and development	\$1,160	\$1,107
Selling, general, and administrative	1,440	1,428
Total	\$2,600	\$2,535

The following table sets forth the pro forma amounts for the year ended December 31, 2005 that would have resulted if the Company had accounted for its employee stock plans under the fair value recognition provisions of FAS 123. The following table does not show the impact that the adoption of FAS 123 would have had on discontinued operations, as these amounts are not considered significant (in thousands):

Net income:		
As reported	\$1	3,064
Add:		
Stock-based compensation expense included in reported net income, net of		
tax		206
Less:		
Total stock-based compensation expense determined under the fair value		
based method, net of tax	(	2,462)
Pro forma net income	\$1	0,808
Basic net income per share:		
As reported	\$	0.58
Pro forma	\$	0.48
Diluted net income per share:		
As reported	\$	0.55
Pro forma	\$	0.45

Activity under the stock option plans is set forth below (in thousands except per share amounts):

	Number of Options Outstanding	Weighted Average Exercise Price per Share (\$)
Balances at December 31, 2004	4,294	14.749
Granted	885	7.487
Cancelled	(457)	2.934
Exercised	(124)	21.253
Balances at December 31, 2005	4,598	13.025
Granted	984	6.96
Cancelled	(190)	15.41
Exercised	(137)	3.26
Balances at December 31, 2006	5,255	12.06
Granted	895	7.90
Cancelled	(654)	9.79
Exercised	(323)	3.92
Balances at December 31, 2007	5,173	12.13

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

At December 31, 2007, the total aggregate intrinsic value of options outstanding and of options exercisable was \$7.5 million and \$5.9 million, respectively. The weighted average fair value of options granted during the years ended December 31, 2007, 2006, and 2005 were \$4.34, \$4.00, and \$3.37 per share, respectively. The fair value of options that vested during the years ended December 31, 2007, 2006, and 2005 were \$1.7 million, \$3.1 million, and \$4.2 million, respectively. Options to purchase 3.5 million, 3.0 million, and 2.2 million shares were exercisable at December 31, 2007, 2006 and 2005, respectively. The following table depicts the population of stock options at range of exercise prices outstanding at December 31, 2007:

(Shares in thousands)	Options Outstanding			Optio	ons 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
\$2.05—2.05	150	6.60	\$ 2.05	125	\$ 2.05
\$2.10—2.28	552	5.34	\$ 2.28	446	\$ 2.28
\$2.39—2.89	379	5.30	\$ 2.53	279	\$ 2.54
\$2.95—3.25	542	6.37	\$ 3.23	486	\$ 3.23
\$3.48—5.55	758	6.55	\$ 5.03	410	\$ 4.68
\$5.57—7.52	533	7.27	\$ 6.64	285	\$ 6.76
\$7.55—8.73	546	9.12	\$ 8.62	32	\$ 7.96
\$8.86—9.61	521	6.69	\$ 8.94	308	\$ 8.93
\$10.15—24.88	517	3.47	\$17.68	481	\$18.21
\$26.25—75.25	675	2.93	\$48.33	675	\$48.33
	<u>5,173</u>	5.89	\$12.13	3,527	\$14.68

The total intrinsic value of options exercised during the years ended December 31, 2007, 2006, 2005 was \$1.3 million, \$0.8 million, and \$0.5 million, respectively. As of December 31, 2007, we had stock-based compensation expense of \$4.2 million related to nonvested stock options not yet recognized, which is expected to be recognized over an estimated weighted average period of 2.79 years.

#### Note 11. Development and License Agreements

#### Restructured Agreements with Baxter and Fenwal

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, 2006 and 2005, the Company recognized development funding revenue of \$2.0 million and \$1.6 million, respectively, under these agreements. Under the agreements, Baxter has been responsible for manufacturing and marketing the platelet system, which is approved for sale in some countries in Europe. The agreements provided for the Company to receive approximately 33.5% of revenue from sales of system disposables after each party is reimbursed for its cost of goods to the extent cost exceeds specific amounts. The Company recognized product sales of \$3.0 million and \$0.5 million in the years ended December 31, 2006 and 2005, respectively.

In February 2005, Baxter and the Company entered into agreements that reaffirmed the previous agreements in certain respects and modified them in other respects (the "2005 agreements"). Under the 2005 agreements,

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

Baxter remained solely responsible for sales and marketing expenses for the products/countries as to which it maintained commercialization rights. For 2005 and 2006, Baxter agreed to fund \$13.1 million of expenses for platelet and plasma system sales and marketing and for activities directed toward CE mark approval of the plasma system. Baxter also agreed to furnish specified levels of personnel to conduct sales and marketing of the platelet system and, upon approval, plasma system in Europe. The Company's agreements with Baxter provided for sales and marketing strategy surrounding Baxter's commercialization rights to be set by a joint Cerus/Baxter governance committee.

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 2005 agreements. Commencing January 1, 2005, each company agreed to bear its own expenses regarding ongoing discussions with the FDA to gain clarity on the remaining steps in the U.S. regulatory process for the platelet system.

Under the 2005 agreements, the Company remained responsible for funding 100% of development expenses for the plasma system, except that \$2.2 million of Baxter's \$13.1 million commitment (described above) may be applied to activities directed toward obtaining CE mark approval of and launch preparation for the plasma system. Baxter agreed to cooperate with the Company to complete certain activities required for the CE mark application. Such activities shall, except for the right to apply such \$2.2 million, be at the Company's expense. For the years ended December 31, 2006 and 2005, the Company applied \$2.0 million and \$1.2 million, respectively, of Baxter's commitment to expenses incurred during the periods directed toward obtaining CE mark approval of the plasma system, which was recognized as development funding revenue.

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

Baxter agreed in the February 2005 agreement to manufacture systems and components, on a cost-plus basis, through 2008. Since the agreements do not require Baxter to manufacture in an FDA-approved facility, the Company will need to undertake additional validation steps before use of such items in the United States. Baxter has agreed to supply only very limited types of components for the prototype red blood cell system.

Effective February 1, 2006, the Company entered into an additional restructuring of its agreements with Baxter related to the INTERCEPT Blood System. Under the terms of the February 2006 agreement, the Company gained worldwide rights to the INTERCEPT Blood System for platelets (the "platelet system") and the INTERCEPT Blood System for plasma (the "plasma system") previously held by Baxter, excluding certain Asian countries covered in agreements with BioOne. As a result of the agreement, the Company records all of the platelet and plasma system revenues.

Prior to entering into the February 2006 agreement, the Company received 33.5 % of the adjusted gross margins from sales of the platelet system, which are shown as product revenue on its consolidated statements of operations. Baxter has agreed to supply certain transition services, including regulatory, technical and administrative support in 2006, at the Company's expense and to conduct certain continued development efforts relating to the plasma system at Baxter's expense. Also as a result of this agreement, the Company repaid a

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

\$4.5 million promissory note and the related accrued interest in 2006. Interest expense was recorded as a component of interest income (expense) and other, net on the Company's consolidated statements of operations. This promissory note had been payable to Baxter since February 2005 and had an original maturity date of December 2006 with interest of 8%.

In March 2007, Baxter sold its Transfusion Therapies business, the unit of Baxter that has performed many of the manufacturing and supply chain activities related to the Company's relationship with Baxter, to a new company, Fenwal Inc. Fenwal has assumed Baxter's obligations to the Company under the manufacturing agreement and the Company is obligated to pay royalties on INTERCEPT Blood System product sales to Fenwal, rather than to Baxter.

#### Agreements with BioOne

In April 2004, the Company made an investment in the common stock of BioOne, a privately held Japanese corporation. BioOne was formed in 2004 to develop technologies to improve the safety of blood products in Asia, and is funded by equity investments from Japanese venture capital firms, other corporations and individual investors.

In June 2004, Baxter and the Company entered into an agreement with BioOne for commercialization of the INTERCEPT Blood System for platelets in parts of Asia. Under the terms of the agreement, BioOne is responsible, at its expense, for seeking regulatory approvals and will have exclusive rights to market and distribute the INTERCEPT Blood System for platelets in Japan, China, Taiwan, South Korea, Thailand, Vietnam and Singapore, following their receipt of regulatory approval in each of those countries. In July 2004 and October 2004, Baxter and the Company each received up-front payments of \$10.0 million from BioOne. The Company's portion of the up-front payments was 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 \$0.0 million, \$2.8 million and \$5.5 million of revenue under this agreement during the years ended December 31, 2007, 2006, and 2005, respectively.

In December 2004, Baxter and the Company signed a letter of intent with BioOne to enter into a definitive agreement for commercialization of the INTERCEPT Blood System for plasma in parts of Asia. Under the letter of intent, the Company received a payment of \$3.0 million from BioOne, which was recorded as deferred revenue as of December 31, 2004. A definitive agreement with BioOne for the plasma system was signed by Baxter and the Company in June 2005, and in December 2005 the Company received additional up-front payments of \$2.0 million in cash and \$5.0 million in BioOne's equity, both of which were recorded upon receipt as deferred revenue to be amortized over the remaining development period. In December 2006, the Company received a milestone payment from BioOne of \$4.5 million in cash and \$5.0 million in BioOne's equity, both of which were in recognition of the Company receipt of a CE mark for the plasma system. The Company evaluates several criteria to determine the fair value of the equity received and to conclude whether or not the facts and circumstances support a fair value for revenue recognition and investment balance. These criteria include, but are not limited to: third-party investor interest and participation in recent equity offerings at current pricing, business outlook of BioOne, and available financial information. Based on this evaluation, the Company recognized the entire \$5.0 million of equity received as revenue in December 2006. Since BioOne is a privately-held Japanese company, it is only obligated to provide the Company with annual financial information at the end of its fiscal year which ends in May. Therefore, although the Company used the best available information at the time, there can be no absolute assurance that facts and circumstances will not change in the future. The Company recognized \$17.7 million and \$1.8 million of revenue under this agreement during the years ended December 31, 2006, and 2005, respectively.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### **December 31, 2007**

Revenues recognized from BioOne represented 0%, 67%, and 51%, of total revenues for the years ending December 31, 2007, 2006, and 2005, respectively. The following table summarizes the milestone and development funding payments and revenue recognized from BioOne (in thousands):

	Total Payments	2007	2006	2005	2004
Platelet	\$10,000	<b>\$</b> —	\$ 2,768	\$5,536	\$1,696
Plasma	19,500		17,714	1,786	
Total	\$29,500	<u>\$</u>	\$20,482	\$7,322	\$1,696

The Company made an additional \$1.1 million investment in BioOne equity securities in July 2004. As a result of dilution from additional concurrent third party investments in BioOne, the Company then held less than 20% of the outstanding voting securities of BioOne and began accounting for its investment in BioOne under the cost method. As partial payment for rights to the plasma system in BioOne's territories, in December 2005 the Company received shares and a warrant, exercisable at a nominal price, for additional shares valued at \$5.0 million based on a concurrent financing with new and existing investors completed by BioOne. At December 31, 2007, the Company holds approximately 15% of the voting securities of BioOne. The Company has evaluated several criteria in determining that it does not have the ability to exercise significant influence over BioOne. As a result of this evaluation, at December 31, 2007, the Company continues to account for its investment under the cost method, as it has concluded that predominant evidence exists to support this conclusion.

During the three months ended June 30, 2007, the Company was notified that BioOne was seeking equity financing from institutional and corporate investors. Subsequent to June 30, 2007, BioOne received equity financing from institutional and corporate investors at a price per share below the Company's carrying value. The Company did not participate in this equity offering. However, as a consequence, the Company recorded a \$9.5 million non-cash impairment charge on the carrying value of its interest in BioOne equity during the three month period ended June 30, 2007. The Company's investment in BioOne, which had been recorded at \$11.2 million as of March 31, 2007, and is included in long-term investment in related party on its balance sheets, was written down to \$1.7 million as of December 31, 2007, which represents the Company's best current estimate of the fair value of its investment in BioOne. To the extent that the criteria used to support the carrying value of the Company's investment in BioOne at December 31, 2007, deteriorates further, it will need to reassess the recorded basis of its investment in BioOne.

#### Cooperative Agreements with the U.S. Armed Forces

Since February 2001, the Company has received awards under cooperative agreements with the Army Medical Research Acquisition Activity division of the Department of Defense. The Company received these awards in order to develop its pathogen inactivation technologies for the improved safety and availability of blood that may be used by the U.S. Armed Forces for medical transfusions. Under the conditions of the agreements, the Company is conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites that are of concern to the U.S. Armed Forces. This funding also supports advanced development of the Company's blood safety technologies. The Company recognized \$3.0 million, \$4.8 million and \$4.1 million of revenue under these agreements during the years ended December 31, 2007, 2006 and 2005, respectively. As of December 31, 2007, the Company has received \$29.9 million of cash payments from these awards.

Revenue recognized from the U.S. Armed Forces represented 27%, 16%, and 30% of total revenue for the years ended December 31, 2007, 2006, and 2005, respectively.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### **December 31, 2007**

#### Note 12. 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 at the enacted rates. Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,		
	2007	2006	
Net operating loss carryforward	\$ 101,300 31,800	\$ 85,500 30,600	
Deferred revenue	_	_	
Capitalized research and development	26,400	25,400	
Certain expenses not currently deductible for tax purposes	1,900	2,200	
Accrued liabilities	200	300	
Stock-based compensation	1,800	900	
Other	2,900	3,000	
Gross deferred tax assets	166,300	147,900	
Valuation allowance	(166,300)	(147,900)	
Net deferred tax assets	<u>\$</u>	<u> </u>	

The valuation allowance increased by \$18.4 million, increased by \$8.0 million and decreased by \$3.8 million for the years ended December 31, 2007, 2006, and 2005, respectively. The Company believes that, based on a number of factors, the available objective evidence creates sufficient uncertainty regarding the realizability of the deferred tax assets such that a full valuation allowance has been recorded. These factors include the Company's history of net losses since its inception, the need for regulatory approval of the Company's products prior to commercialization, expected near-term future losses and the absence of taxable income in prior carryback years. The Company expects to maintain a full valuation allowance until circumstances change. Undistributed earnings of the Company's foreign subsidiary, Cerus Europe B.V., amounted to approximately \$0.17 million at December 31, 2007. The earnings are considered to be permanently reinvested and accordingly, no deferred U.S. income taxes have been provided thereon. Upon distribution of those earnings in the form of dividends or otherwise, the Company would be subject to U.S. income tax. At the Federal statutory income tax rate of 35%, this would result in taxes of approximately \$.06 million.

Although management's operating plans assume, beyond the near-term, taxable and operating income in future periods, management's evaluation of all available information in assessing the realizability of the deferred tax assets in accordance with FAS 109, indicates that such plans were subject to considerable uncertainty. Therefore, the valuation allowance was adjusted to fully reserve the Company's deferred tax assets. The Company will continue to assess the realizability of the deferred tax assets based on actual and forecasted operating results. For the year ended December 31, 2007, the Company reported net losses of \$45.3 million on its consolidated statement of operations and calculated taxable losses for both federal and state taxes. The difference between reported net loss and taxable loss are due to temporary differences between U.S. GAAP and the respective tax laws.

At December 31, 2007, the Company had net operating loss carryforwards of approximately \$255.8 million for federal and \$238.8 million for state income tax purposes. The Company also had research and development tax credit carryforwards of approximately \$21.6 million for federal income tax purposes and approximately \$15.3 million for state income tax purposes at December 31, 2007. The federal net operating loss and tax credit carryforwards expire between the years 2008 and 2027. The state net operating loss carryforwards expire between the years 2012 and 2017. The state research and development credits do not expire.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

The utilization of net operating loss carryforwards, as well as research and development credit carryforwards, is limited by current tax regulations. These net operating loss carryforwards, as well as research and development credit carryforwards, will be utilized in future periods if sufficient income is generated. The Company believes it more likely than not that its tax positions would be recognized upon review by a taxing authority having full knowledge of all relevant information. The Company's ability to utilize certain loss carryforwards and certain research credit carryforwards are subject to limitations pursuant to the ownership change rules of Internal Revenue Code Section 382.

#### Note 13. 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, 2007, 2006 and 2005.

#### Note 14. Segment Information and Geographic Information

At December 31, 2007, the Company operates only one segment, blood safety. Prior to its November 2007 sale of its former immunotherapy business to Anza Therapeutics, the Company operated two segments: blood safety and immunotherapy. Results for the years ended December 31, 2007, 2006, and 2005 have been restated to show the Company's former immunotherapy segment as a discontinued operation. Results for the Company's remaining segment, the blood safety segment, are the same as its consolidated results. The Company's Chief Executive Officer is the chief operating decision maker who evaluates performance based on the net revenues and operating income (loss) of the blood safety segment.

The Company's operations outside of the United States include a wholly-owned subsidiary headquartered in Europe. The Company's operations in the United States are responsible for the research and development and global commercialization of the INTERCEPT Blood System, while operations in Europe are responsible for the commercialization efforts of the platelet and plasma systems in Europe and the Middle East. Essentially all of the Company's long-tived assets are in the United States. Revenues are attributed to each region based on the location of the customer, and in the case of non-product revenues, on the location of the collaboration partner. Revenues by region are as follows (in thousands):

2007	2006	2005
\$ 3,029	\$ 6.853	\$ 6.033
	2,975	· <u> </u>
	20,482	7,464
\$11,044	\$30,310	\$13,497
	\$ 3,029 8,015	\$ 3,029 \$ 6,853 8,015 2,975

Assets are attributed to each region based on the physical location of the asset and are as follows (in thousands):

	2007	2006
Total Assets:		
United States	\$62,560	\$113,628
Europe	15,649	2,189
Totals	\$78,209	\$115,817

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

#### Note 15. Discontinued Operation

In November 2007, the Company sold its immunotherapy business to Anza Therapeutics, Inc. ("Anza"), which received initial funding from a syndicate of venture capital firms, including Kleiner Perkins Caufield & Byers, Sofinnova Ventures and Versant Ventures. The Company sold certain tangible and intangible assets in connection with this sale, consisting primarily of certain laboratory equipment and intellectual property. In exchange for the tangible and intangible assets, the Company received 5,000,000 shares of Series AA Preferred Stock, constituting an equity interest of approximately 17.8% (15.5% fully diluted) of Anza's equity. Of this, up to 1,000,000 shares is to be returned to Anza if the expected size of certain grants is not received by Anza. Subject to the satisfaction of milestones with regard to the timing and magnitude of a potential corporate partnering relationship between Anza and an identified multi-national pharmaceutical company, the Company is eligible to receive up to an additional \$1.5 million of Series AA Preferred Stock in Anza or, under certain circumstances, in cash. The Series AA Preferred Stock is non-voting and has no rights of representation on Anza's board of directors, but otherwise generally carries the same rights and privileges as the Series A Preferred Stock of Anza purchased by the venture capital investors. In addition to equity, the Company is eligible to receive future cash milestone payments of up to \$94 million, as well as low single-digit royalty payments, if certain vaccine candidates generated from the transferred assets are successfully developed and commercialized. Of the milestone payments for which the Company is eligible, \$90 million is payable only upon reaching specified annual sales levels within a certain number of years of product launch for the first two products brought to market incorporating Anza's proprietary Listeria technology.

As a result of the sale of its immunotherapy business, the Company recorded a loss of \$0.4 million representing the carrying value of the tangible assets sold. Prior to the sale of the immunotherapy business, the Company had expensed all costs associated with its immunotherapy business in the periods incurred. The Company has not assigned any value to the equity interest it received in Anza, due to the lack of marketability of the equity received, the early stage of development of Anza's potential products, and the high degree of uncertainty regarding the future marketability of the equity the Company received, and the uncertainty that the Company will receive any milestone or royalty payments, which are dependent on Anza's successful commercialization of certain product candidates.

The Company has accounted for its immunotherapy business as a discontinued operation, and has restated its financial statements for prior periods to reflect the discontinued operation. The Company is providing certain transition services to Anza, generally for less than one year, under terms of a transition services agreement in which Anza will reimburse the Company for its direct costs associated with providing such services. The transition services the Company is providing to Anza are generally ancillary in nature and do not involve Anza's core business or any scientific research or development. We also subleased 14,800 square feet to Anza under a sublease which expires on October 31, 2008, unless terminated sooner.

The following table summarizes the results of the Company's former immunotherapy segment for the three years ended December 31, 2007:

		Inded Decem	ber 31,
(in thousands, except percentage)	2007	2006	2005
Revenue	\$ 4,356	\$ 5,270	\$10,874
Operating expenses	10,176	12,401	12,267
Loss from discontinued operations	(5,820)	(7,131)	(1,393)
Loss from sale of discontinued operations	(384)		
Net loss from discontinued operations	\$ (6,204)	<u>\$(7,131)</u>	\$(1,393)

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### December 31, 2007

Note 16. Quarterly Financial Information (Unaudited and in thousands except per share amounts)

		Three M	Months Ended	
	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007
Revenue:				
Product revenue	\$ 1,187	\$ 1,671	\$ 2,762	\$ 2,395
agreements	1,064	1,551	414	
Total revenue	2,251	3,222	3,176	2,395
Cost of product revenue	824	1,067	1,673	1,664
Gross profit Operating expenses	1,427	2,155	1,503	731
Research and development	3,266	3,559	4,006	4,126
Selling, general, and administrative Impairment of long-term investment in	5,322	6,151	5,631	7,471
related party	_	9,450	_	_
Total operating expenses	8,588	19,160	9,637	11,597
Operating loss	(7,161)	(17,005)	(8,134)	(10,866)
Other income, net	1,088	<u>996</u>	1,334	648
Net loss from continuing operations	\$(6,073)	\$(16,009)	\$(6,800)	\$(10,218)
Discontinued operations:  Loss from discontinued operations  Loss from sale of discontinued	(735)	(1,906)	(2,351)	(828)
operations				(384)
Net loss from discontinued operations	(735)	(1,906)	(2,351)	(1,212)
Net loss	\$(6,808)	\$(17,9 <u>15</u> )	\$(9,151)	\$(11,430)
Net loss from continuing operations per share—basic	\$ (0.19)	\$ (0.50)	\$ (0.21)	\$ (0.32)
Net loss from continuing operations per share—diluted	\$ (0.19)	\$ (0.50)	\$ (0.21)	\$ (0.32)
Net loss from discontinued operations per share—basic	\$ (0.02)	\$ (0.06)	\$ (0.08)	\$ (0.04)
Net loss from discontinued operations per	e (0.03)	e (0.06)	¢ (0.00)	<b>c</b> (0.04)
share—diluted	\$ (0.02) \$ (0.21)	\$ (0.06) \$ (0.56)	\$ (0.08) \$ (0.29)	\$ (0.04) \$ (0.36)
Net loss per share—diluted	\$ (0.21)	\$ (0.56)	\$ (0.29)	\$ (0.36)

# $NOTES\ TO\ CONSOLIDATED\ FINANCIAL\ STATEMENTS — (Continued)$

# **December 31, 2007**

	Three Months Ended			
	March 31, 2006	June 30, 2006	September 30, 2006	December 31, 2006
Revenue:				
Milestone and development funding	\$ 121	\$ 754	\$ 529	\$ 613
Revenue from related party Government grants and cooperative	3,437	3,437	2,053	11,555
agreements	382	_	3,892	562
Product revenue	479	776	794	926
Total revenue	4,419	4,967	7,268	13,656
Cost of product revenue	182	281	373	705
Gross profit Operating expenses	4,237	4,686	6,895	12,951
Research and development	3,437	4,709	3,960	3,930
Selling, general, and administrative	3,160	4,142	3,631	4,149
Total operating expenses	6,597	8,851	7,591	8,079
Operating income (loss)	(2,360)	(4,165)	(696)	4,872
Other income, net	2,053	868	915	865
Net income (loss) from continuing	<del></del> _		<del></del>	
operations	<u>\$ (307)</u>	<u>\$(3,297)</u>	\$ 219	\$ 5,737
Discontinued operations:				
Loss from discontinued operations	(623)	(1,775)	(2,006)	_(2,727)
Net income (loss)	\$ (930)	\$(5,072)	\$(1,787)	\$ 3,010
Net income (loss) from continuing operations				
per share—basic	\$ (0.01)	\$ (0.12)	\$ 0.01	\$ 0.20
Net income (loss) from continuing operations				
per share—diluted	\$ (0.01)	\$ (0.12)	\$ 0.01	\$ 0.19
Net loss from discontinued operations per	*		<b>+</b>	4 (0.00)
share—basic	\$ (0.03)	\$ (0.06)	\$ (0.07)	\$ (0.10)
Net loss from discontinued operations per	e (0.02)	e (0.06)	e (0.07)	e (0.00)
share—diluted	\$ (0.03) \$ (0.04)	\$ (0.06) \$ (0.18)	\$ (0.07) \$ (0.06)	\$ (0.09) \$ 0.10
Net income (loss) per share—diluted	\$ (0.04)	\$ (0.18)	\$ (0.06) \$ (0.06)	\$ 0.10
riet meome (10ss) per snare—anuteu	\$ (U.U4)	φ (0.10)	\$ (0.00)	φ U.1U

#### **SIGNATURES**

Pursuant to the requirement of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Concord, State of California, on the 26th day of February 2008.

#### **CERUS CORPORATION**

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

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

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

Signature	<u>Title</u>	Date
/s/ CLAES GLASSELL Claes Glassell	President, Chief Executive Officer and Director (Principal Executive Officer)	February 26, 2008
/s/ WILLIAM J. DAWSON William J. Dawson	Chief Financial Officer and Vice President, Finance (Principal Financial and Accounting Officer)	February 26, 2008
/s/ B. J. Cassin	Chairman of the Board	February 26, 2008
B. J. Cassin		
/s/ TIMOTHY B. ANDERSON Timothy B. Anderson	Director	February 26, 2008
/s/ LAURENCE M. CORASH Laurence M. Corash, M.D.	Director	February 26, 2008
/s/ BRUCE C. COZADD  Bruce C. Cozadd	Director	February 26, 2008
/s/ WILLIAM R. ROHN William R. Rohn	Director	February 26, 2008
/s/ GAIL SCHULZE  Gail Schulze	Director	February 26, 2008

#### INDEX TO EXHIBITS

Exhibit Number	Description of Exhibit
3.1.1(4)	Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
3.2 (14)	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.
10.6 (1)	Amended and Restated Investors' Rights Agreement, dated April 1, 1996, among Cerus and certain investors.
10.7 (1)	Industriał Real Estate Lease, dated October 1, 1992, between Cerus and Shamrock Development Company, as amended on May 16, 1994 and December 21, 1995.
10.8 (1)	Real Property Lease, dated August 8, 1996, between Cerus and S.P. Cuff.
10.9 (1)	Lease, dated February 1, 1996, between Cerus and Holmgren Partners.
10.10(1)	First Amendment to Common Stock Purchase Agreement, dated December 9, 1996, between Cerus and Baxter Healthcare Corporation.
10.11(2)†	License Agreement, dated as of November 30, 1992, by and among the Company, Miles Inc. and Diamond Scientific Corporation.
10.12(3)	Series B Preferred Stock Purchase Agreement, dated as of June 30, 1998, by and between Cerus and Baxter Healthcare Corporation.
10.13(4)	Stockholder Rights Plan, dated November 3, 1999.
10.14(13)*	1999 Equity Incentive Plan, as amended, adopted April 30, 1999, approved by stockholders July 2, 1999.
10.15(5)*	Employment Agreement with Howard G. Ervin.
10.16(6)	Lease, dated December 17, 1999 between Cerus and Redwoods Office Center, L.P.
10.17(6)	Lease, dated October 12, 2001 between Cerus and California Development, Inc.
10.18(7)	Loan and Security Agreement, dated November 15, 2002, between Cerus and Baxter Capital Corporation.
10.19(8)*	1999 Non-Employee Directors' Stock Option Sub-Plan, amended December 4, 2002.
10.20(9)†	Collaboration and License Agreement, dated April 20, 2004, between Cerus Corporation and MedImmune, Inc.
10.21(9)*	Employment Agreement, dated August 5, 2004, between Cerus Corporation and Claes Glassell.
10.22(10)*	Employment Agreement, dated July 22, 2004, between Cerus Corporation and William J. Dawson.
10.23(11)†	Restructuring Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.24(11)†	License Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.

Exhibit Number	Description of Exhibit
10.25(11)†	Manufacturing and Supply Agreement, dated as of February 2, 2005, by and among Cerus, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.26(12)*	Bonus Plan for Senior Management of Cerus Corporation, dated January 1, 2006.
10.27(12)†	Commercialization Transition Agreement, dated as of February 12, 2006, by and among Cerus Corporation, Baxter Healthcare S.A. and Baxter Healthcare Corporation.
10.28(16)†	Asset Transfer and License Agreement, dated November 20, 2007, by and between Cerus Corporation and Anza Therapeutics, Inc.
10.29(16)*	Offer Letter to Gail Schulze, dated October 15, 2007.
10.30(16)*	Base Salaries for Fiscal Year 2007 for Named Executive Officers.
10.31(15)*	Cerus Corporation Change of Control Severance Benefit Plan.
21.1	List of Registrant's subsidiaries.
23.1	Consent of 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.
- (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' Current Report on Form 8-K, dated June 30, 1998.
- (4) Incorporated by reference to Cerus' Current Report on Form 8-K, dated November 3, 1999.
- (5) Incorporated by reference to Cerus' Annual Report on Form 10-K, for the year ended December 31, 2000.
- (6) Incorporated by reference to Cerus' Annual Report on Form 10-K, for the year ended December 31, 2001.
- (7) Incorporated by reference to Cerus' Annual Report on Form 10-K, for the year ended December 31, 2002.
- (8) Incorporated by reference to Cerus' Quarterly Report on Form 10-O for the quarter ended March 31, 2003.
- (9) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.
- (10) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.
- (11) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.
- (12) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2006.
- (13) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.
- (14) Incorporated by reference to Cerus' Current Report on Form 8-K, dated April 26, 2007.
- (15) Incorporated by reference to Cerus' Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.
- (16) Filed herewith.

# Cerus Corporation Subsidiaries of the Registrant

Legal Name	Jurisdiction of Formation
Cerus Europe B.V.	Netherlands

#### CONSENT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC

#### **ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements on Forms S-8 (Nos. 333-145007, 333-136452, 333127541, 333-125043, 333-109170, 333-92254, 333-63132, 333-42588, 333-84497, 333-74991, and 333-27097) of Cerus Corporation pertaining to the 1996 Equity Incentive Plan, Employee Stock Purchase Plan, 1998 Non-Officer Stock Option Plan and 1999 Equity Incentive Plan, and in the Registration Statements on Form S-3 (Nos. 333-93481, 333-47224, 333-61460, 333-61910, 333-67286, 333-127541, 333-75413, and 333-72185) and the related Prospectuses of Cerus Corporation of our reports dated February 26, 2008, with respect to the financial statements of Cerus Corporation and the effectiveness of internal control over financial reporting of Cerus Corporation, included in this Annual Report (Form 10-K) for the year ended December 31, 2007.

/s/ ERNST & YOUNG LLP

Palo Alto, California February 26, 2008

#### CEO CERTIFICATION

#### I, Claes Glassell, certify that:

- 1. I have reviewed this annual report on Form 10-K of Cerus Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all
  material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods
  presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2008

/s/ CLAES GLASSELL

Claes Glassell Chief Executive Officer

#### CFO CERTIFICATION

#### I, William J. Dawson, certify that:

- 1. I have reviewed this annual report on Form 10-K of Cerus Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our
    conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this
    report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2008

/s/ WILLIAM J. DAWSON

William J. Dawson Chief Financial Officer

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Claes Glassell, Chief Executive Officer of Cerus Corporation (the "Company") and William J. Dawson, the Chief Financial Officer of the Company, each hereby certify that, to the best of his knowledge:

- 1. The Company's Annual Report on Form 10-K for the period ended December 31, 2007, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act, and
- 2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 26th day of February, 2008.

/s/ CLAES GLASSELL

/s/ WILLIAM J. DAWSON

Claes Glassell Chief Executive Officer William J. Dawson Chief Financial Officer

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

# r, Boston, Massachusetts

# Executive Management & Board of Directors

Executive Management
Claes Glassell
President and Chief Executive Officer

William M. Greenman President, Cerus Europe

Laurence M. Corash, M.D. Senior Vice President and Chief Medical Officer

William J. Dawson Vice President, Finance and Chief Financial Officer

Joseph J. Eiden, M.D. Vice President, Clinical Research and Medical Affairs

Howard G. Ervin Vice President, Legal Affairs

Suzanne C. Margerum Vice President, Development and Manufacturing

Carol M. Moore Vice President, Regulatory Affairs and Quality

Lori L. Roll Vice President, Administration and Corporate Secretary

Board of Directors B.J. Cassin Chairman of the Board, Private Venture Capitalist

Timothy B. Anderson Former Senior Vice President, Baxter International Inc.

Laurence M. Corash, M.D.
Senior Vice President and Chief Medical Officer

Bruce C. Cozadd Executive Chairman, Jazz Pharmaceuticals, Inc.

Claes Glassell President and Chief Executive Officer

William R. Rohn Former Chief Operating Officer, Biogen Idec Inc.

Gail Schulze Former Chief Executive Officer YM Biosciences US

#### **Corporate Information**

Corporate Headquarters 2411 Stanwell Drive Concord, California 94520 Telephone: (925) 288-6000 Fax: (925) 288-6001 www.cerus.com

European Headquarters Stationsstraat 79-D 3811 MH Amersfoort Netherlands Telephone: 31 33 496 0600 Fax: 31 33 496 0606

Corporate Counsel
Cooley Godward Kronish LLP
Palo Alto, California

Patent Counsel
Morrison & Foerster LLP
Palo Alto, California

Auditors Ernst & Young LLP Palo Alto, California

Registrar and Transfer Agent Wells Fargo Bank, N.A. 161 North Concord South St. Paul, Minnesota 55075 Telephone: (800) 401-1957 Fax: (651) 450-4033

#### Annual Report on Form 10-K

A copy of the company's Annual Report on Form 10-K as filed with the Securities and Exchange Commission is available without charge on request to:

Investor Relations Department Cerus Corporation 2411 Stanwell Drive Concord, California 94520 Telephone: (925) 288-6000

Stock Information
Common stock, traded on the Nasdaq
Stock Market under the symbol: CERS

Annual Meeting of Stockholders 9:00 a.m., Monday, June 2, 2008 Cerus Corporation 2411 Stanwell Drive Concord, California 94520

### Forward-looking Statement

Statements in this annual report regarding future clinical trials, future regulatory filings, potential efficacy of products, potential collaborations, future product development and commercial potential are forward-looking statements that involve risks and uncertainties. Actual results could differ materially from these forward-looking statements as a result of certain factors, including the risks and uncertainty of the timing and results of clinical trials and other development activities, actions by regulatory authorities at any stage of the development process, additional financing activities, performance by partners, manufacturing, market acceptance of any products, competitive conditions, legal proceedings and other factors discussed in the Company's most recent filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2007. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this annual report. The Company does not undertake any obligation to update any forward-looking statements as a result of new information, future events, changed assumptions or otherwise.

Cerus, INTERCEPT and INTERCEPT Blood System are trademarks of Cerus.

# CERUS

